(1)
Supreme Court, U.S.
FILED
981768 MAY 3 1999
OFFICE OF THE

No. 98-

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR A WRIT OF CERTIORARI

SCOTT BURESH
FRED FELLER
Buresh, Kaplan, Jang, Feller & Austin
2298 Durant Ave.
Berkeley, CA 94704
(510) 548-7474

KENNETH S. GELLER
Counsel of Record
ALAN E. UNTEREINER
Mayer, Brown & Platt
1909 K Street, N.W.
Washington, DC 20006
(202) 263-3000

GEORGE P. NOEL
Noel & Hackett
P.O. Box 1590
Media, PA 19063
(610) 892-7700

Counsel for Petitioner

1048

QUESTIONS PRESENTED

1. Whether a state tort claim collaterally attacking a decision of the Food and Drug Administration to permit the marketing of a medical device on the ground that approval was obtained though a "fraud on the agency" is expressly or impliedly preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

2. Whether the Medical Device Amendments, which expressly preempt "any" state requirement that "relates to the safety or effectiveness" of a device and is "different from, or in addition to" a federal requirement (21 U.S.C. § 360k(a)), exclude state requirements that are imposed through tort laws of general applicability.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent companies or nonwholly owned subsidiaries.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	(I)
RULE 29.6 STATEMENT	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	1
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	1
STATEMENT	1
A. The Regulatory Structure of the Medical Device Amendments	3
B. The FDA's Clearance of the Bone Screws	5
C. The Orthopedic Bone Screw Product Liability Litigation	6
D. The Court of Appeals' Decision	8
REASONS FOR GRANTING THE PETITION	9
I. The Circuits Are Divided Over Whether "Fraud on the Agency" Claims Are Preempted By Federal Law	11
A. This Case Squarely Presents the Conflict	11
B. The Issue Presented by the Conflict is Recurring and of Great Practical Importance	16
II. The Decision Below Reflects Widespread Uncertainty Over the Meaning of *Medtronic* v. *Lohr*, Which This Court Alone Can Dispel	19

TABLE OF CONTENTS — CONTINUED

Page

III. The Decision Below Is Incorrect 25

A. The Court Below Erred In Concluding That "Fraud on the Agency" Claims Are Not Subject To Preemption Under *Medtronic* . 25

B. The Court Below Erred In Holding That State Tort Claims Are Not Preempted Because of Their Generality 29

CONCLUSION 30

TABLE OF AUTHORITIES

Cases: **Page(s)**

Armstrong v. *Optical Radiation Corp.*, 50 Cal. App.4th 580 (1996) 24

Baird v. *American Med. Optics*, 713 A.2d 1019 (N.J. 1998) 24

Baldwin v. *Alabama*, 472 U.S. 372 (1985) 25

Berish v. *Richards Med. Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996) 23

Brannan v. *United Student Aid Funds*, 94 F.3d 1260 (9th Cir. 1996), cert. denied, 521 U.S. 1106 (1997) 20

Carey v. *Shiley, Inc.*, 32 F. Supp. 2d 1093 (S.D. Iowa 1998) 15

Chmielewski v. *Stryker Sales Corp.*, 966 F. Supp. 839 (D. Minn. 1997) 23

Colorado Public Utilities Comm'n v. *Harmon*, 951 F.2d 1571 (10th Cir. 1991) 20

Commonwealth Edison Co. v. *Vega*, 1999 WL 212210 (7th Cir. April 13, 1999) 20

Connelly v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) 15, 24

Dutton v. *AcroMed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997) 15, 24

Duvall v. *Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. 1996) 11, 22

Easterling v. *Cardiac Pacemakers, Inc.*, 986 F. Supp. 366 (E.D. La. 1997) 23

TABLE OF AUTHORITIES — CONTINUED

Page(s)

Elizabeth Blackwell Health Ctr. for Women v. *Knoll*, 61 F.3d 170 (3d Cir. 1995) 20

Evraets v. *Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779 (1994) 12

Freightliner Corp. v. *Myrick*, 514 U.S. 280 (1995) 13, 29

Fry v. *Allergan Med. Optics*, 695 A.2d 511 (R.I.), cert. denied, 118 S. Ct. 374 (1997) 24

Geier v. *American Honda Motor Co.*, 166 F.3d 1236 (D.C. Cir. 1999) 23

Goodlin v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) . . . . . *passim*

Green v. *Dolsky*, 685 A.2d 110 (Pa. 1996), cert. denied, 520 U.S. 1168 (1997) 15, 24

Grunbeck v. *Dime Svg. Bank*, 74 F.3d 331 (1st Cir. 1996) 20

Gustafson v. *City of Lake Angelus*, 76 F.3d 778 (6th Cir. 1996) 20

H.J., Inc. v. *Northwestern Bell Tel. Co.*, 954 F.2d 485 (8th Cir. 1992) 12

Hernandez v. *Coopervision, Inc.*, 691 So.2d 639 (Fla. Dist. Ct. App. 1997) 23

Hoelck v. *ICI Americas, Inc.*, 584 N.W.2d 52 (Neb. Ct. App.), review denied (Oct. 28, 1998) 15

In re Orthopedic Bone Screw Prods Liab. Litig., 1995 WL 764580 (E.D. Pa. Dec. 14, 1995) 17

TABLE OF AUTHORITIES — CONTINUED

Page(s)

Kernats v. *Smiths Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct. 1996), cert. denied, 118 S. Ct. 684 (1998) 20, 24

Kuiper v. *American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), cert. denied, 118 S. Ct. 1839 (1998) . 10, 11, 15, 16

Lake v. *TPLC*, 1 F. Supp. 2d 84 (D. Mass. 1998) 23

Lakie v. *SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997) 24

Lewis v. *Brunswick Corp.*, 107 F.3d 1494 (11th Cir. 1997), cert. dismissed, 118 S. Ct. 1793 (1998) 10, 11, 15, 17

Martin v. *Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997), cert. denied, 118 S. Ct. 850 (1998) 11, 22, 24

Massachusetts v. *United States Dep't of Transp.*, 93 F.3d 890 (D.C. Cir. 1996) 20

Mears v. *Marshall*, 944 P.2d 984 (Or. Ct. App. 1997) 14, 15, 24

Mears v. *Marshall*, 905 P.2d 1154 (Or. Ct. App. 1995), vacated, 921 P.2d 966 (Or. 1996) 12

Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) . . . . . *passim*

Michael v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 516 U.S. 815 (1995) . . . . . *passim*

TABLE OF AUTHORITIES — CONTINUED

Page(s)

Mitchell v. *Collagen Corp.*, 126 F.3d 902 (1997), cert. denied, 118 S. Ct. 1300 (1998) . . . . . *passim*

Mitchell v. *Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), vacated, 518 U.S. 1030 (1996) 12, 13, 28

Morales v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) 30

Niehoff v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 118 S. Ct. 1187 (1998) 24

Oeffler v. *Miles, Inc.*, 642 N.Y.S.2d 761 (N.Y. Sup. Ct. 1996) 12

Oja v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) 11, 22

Ortho Pharm. Corp. v. *Cosprophar, Inc.*, 32 F.3d 690 (2d Cir. 1994) 4

Papas v. *Upjohn Co.*, 985 F.2d 516 (11th Cir.), cert. denied, 510 U.S. 913 (1993) 12

Papike v. *Tambrands, Inc.*, 107 F.3d 737 (9th Cir.), cert. denied, 118 S. Ct. 166 (1997) . 11, 20, 22, 24

Pilot Life Ins. Co. v. *Dedeaux*, 481 U.S. 41 (1987) 30

Reeves v. *AcroMed Corp.*, 44 F.3d 300 (5th Cir.), cert. denied, 515 U.S. 1104 (1995) 12, 13

Richman v. *W.L. Gore & Assoc.*, 988 F. Supp. 753 (S.D.N.Y. 1997) 23

TABLE OF AUTHORITIES — CONTINUED

Page(s)

San Diego Bldg. Trades Council v. *Garmon*, 359 U.S. 236 (1959) 30

Scott v. *CIBA Vision Corp.*, 38 Cal. App. 4th 307 (1995) 12

Sowell v. *Bausch & Lomb, Inc.*, 230 A.D.2d 77 (N.Y. App. Div. 1997) 24

Steele v. *Collagen Corp.*, 54 Cal. App.4th 1474 (1998) 23

Symens v. *SmithKline Beecham Corp.*, 152 F.3d 1050 (8th Cir. 1998) 23

Taffert v. *The Southern Co.*, 967 F.2d 1483 (11th Cir. 1992) 12

Talbott v. *C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), cert. dismissed, 517 U.S. 1230 (1996) . . . 12, 13, 26

Teper v. *Miller*, 82 F.3d 989 (11th Cir. 1996) 20

Time Warner Cable v. *Doyle*, 66 F.3d 867 (7th Cir. 1995) 20

Walker v. *Johnson & Johnson Vision Prods, Inc.*, 552 N.W.2d 679 (Mich. Ct. App. 1996) 24

Washington Legal Found. v. *Friedman*, 36 F. Supp. 2d 16 (D.D.C. 1999) 4

Wegoland Ltd. v. *Nynex Corp.*, 27 F.3d 17 (2d Cir. 1994) 12

TABLE OF AUTHORITIES — CONTINUED

Page(s)

Weiland v. *Telectronics Pacing Sys., Inc.*, 704 N.E.2d 854 (Ill. App. Ct. 1998), appeal allowed (Ill. Mar. 31, 1999) (Table, No. 86903) . . 23

Welchert v. *American Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995) 12

Wilson v. *Bradlees of New England, Inc.*, 96 F.3d 552 (1st Cir. 1996), cert. denied, 519 U.S. 1149 (1997) 23

Worm v. *American Cyanimid Co.*, 5 F.3d 744 (4th Cir. 1993) 12

Worthy v. *Collagen*, 967 S.W.2d 360 (Tex. 1998) 24

Wutzke v. *Schwaegler*, 940 P.2d 1386 (Wash. Ct. App. 1997), review denied, 953 P.2d 96 (Wash. 1998) 24

Constitutional and Statutory Provisions:

U.S. Const. art. VI, cl. 2 1

7 U.S.C. § 136v(b) 16

15 U.S.C. § 1203(a) 16

15 U.S.C. § 1261 note (b)(1)(A) 16

15 U.S.C. § 1392(d) 16

15 U.S.C. § 1476(a) 16

15 U.S.C. § 2075(a) 16

21 U.S.C. § 331q(2) 26

21 U.S.C. § 336 26

TABLE OF AUTHORITIES — CONTINUED

Page(s)

21 U.S.C. § 337(a) 26

21 U.S.C. § 360c(i)(1)(E)(i) 27

21 U.S.C. § 360e(b)(1)(B) 3, 17, 27, 29

21 U.S.C. § 360k . . . . . *passim*

21 U.S.C. § 360ss 16

21 U.S.C. § 360aaa 3, 19

21 U.S.C. § 396 4

46 U.S.C. § 4306 16

21 C.F.R. § 10.25 18

21 C.F.R. § 10.30 18

21 C.F.R. § 10.33 18

21 C.F.R. § 10.35 18

21 C.F.R. § 801.4 27

21 C.F.R. § 807.87 (1986) 4, 27

21 C.F.R. § 807.87(e) 27

21 C.F.R. § 807.87(*l*) 26

21 C.F.R. § 807.92 4

21 C.F.R. § 807.93 4

21 C.F.R. § 808.1(d)(1) 20

56 Fed. Reg. 46191 (1991) 26

59 Fed. Reg. 59820 (1994) 5, 18

TABLE OF AUTHORITIES — CONTINUED

Page(s)

60 Fed. Reg. 51946 (1995) 6

63 Fed. Reg. 40025 (1998) 3, 17

63 Fed. Reg. 64556 (1998) 19

Pub. L. No. 101-629, Stat. 4511 (1990) 4

TABLE OF AUTHORITIES — CONTINUED

Page(s)

Other Authorities:

Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 77 (1998) 5, 6

FDA Drug Bull. 12:4-5 (1982) 5, 18

Food & Drug Admin., Update on Pedicle Screws (1993) 5, 6

Physicians' Desk Reference Companion Guide (1998) 18

PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-32a) is reported at 159 F.3d 817. The opinion of the district court (App., *infra*, 33a-44a), which was incorporated in the order granting petitioner's motion for dismissal (App., *infra*, 45a), is unreported. The original opinion of the district court (App., *infra*, 46a-53a) is unreported.

JURISDICTION

The court of appeals' judgment was entered on November 19, 1998. A timely petition for rehearing was denied on February 3, 1999 (App., *infra*, 57a-58a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the Constitution provides in relevant part: "[T]he Laws of the United States * * * shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

The relevant provision of the Medical Device Amendments, 21 U.S.C. § 360k, is reproduced at App., *infra*, 59a.

STATEMENT

This case raises important, recurring questions relating to the preemptive scope of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k(a), the meaning of this Court's fractured decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and the validity of efforts by litigants to circumvent Congress's express preemption commands through state tort claims asserting that federal administrative determinations should be disregarded because they were the product of "fraud on the agency."

In 1976, Congress greatly expanded the authority of the

Food and Drug Administration (FDA) to regulate medical devices, such as heart pacemakers and orthopedic bone screws, by enacting the MDA. To protect the uniformity of the federal regulatory scheme, the MDA provides that no State may impose any requirement relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a). In *Medtronic*, this Court interpreted the MDA's preemption provision, but that opinion has engendered widespread conflict and confusion in the lower courts, as reflected in the decision below.

The first conflict, which the court below expressly recognized, concerns whether the MDA preempts a state tort claim that a manufacturer "defrauded" the FDA by making misrepresentations during the regulatory approval process. In contrast to the Seventh and Eleventh Circuits, the Third Circuit has held that so-called "fraud on the agency" claims are not prohibited attempts under state law to second-guess the determinations of a federal agency. If permitted, "fraud on the agency" claims would allow state judges and lay jurors to create havoc with the federal regulatory scheme by deciding that an administrative agency's decision should be ignored even where the agency itself, in full possession of the relevant facts, does not believe that any fraud was committed. As Judge Cowen stated in dissent (App., *infra*, 32a), "[i]t seems very unlikely that Congress intended a state cause of action to intrude so much both in the enforcement of the FDCA's regulatory scheme and in the severity of the penalties attached to a violation."

The second conflict concerns an even more fundamental question raised but not settled by *Medtronic*: whether the MDA can ever preempt a state tort claim of general applicability. The Third Circuit, like the Tenth Circuit, has held that the MDA was not meant to preempt such claims, but the Fourth, Sixth, Seventh and Ninth Circuits have reached the

opposite conclusion. Both of these issues merit further review.

A. The Regulatory Structure of the Medical Device Amendments

The MDA divides medical devices into three classifications based on the possible risks of harm. Devices such as tongue depressors, which present little likelihood of illness or injury, are designated as Class I and subjected only to minimal regulation, or "general controls." 21 U.S.C. § 360c(a)(1)(A). Potentially more dangerous devices, such as tampons, which are classified as Class II, face increased regulation but can still be marketed without FDA approval. *Id.* § 360c(a)(1)(B). The FDA designates as Class III those devices that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or which "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C). All post-1976 devices, including the orthopedic bone screws at issue here,[1] are initially automatically considered Class III devices and cannot be marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Manufacturers may obtain permission to market Class III devices in either of two ways. First, the FDA may grant approval after a thorough premarket approval (PMA) process, in which the manufacturer must present the FDA with "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e. Second, to allow competition with "grandfathered" devices that were on the market in 1976 when the MDA took effect, the FDA may permit marketing of a new device if the manufacturer submits a "premarket

---

[1] After these suits were filed, many of the bone screws challenged by plaintiffs were reclassified as Class II devices as part of pedicle screw systems. 63 Fed. Reg. 40025, 40027 (1998).

notification" showing that the device is "substantially equivalent" to a pre-1976 device. *Id.* §§ 360e(b)(1)(B), 360(k), 360c(f)(1)(B). The "premarket notification" route is often referred to as the "510(k)" process, after the section number in the original act. See *Medtronic*, 518 U.S. at 478.

The FDA has established detailed requirements for manufacturers' Section 510(k) notifications. See 21 C.F.R. § 807.87 (1986).[2] Manufacturers must submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use"; supporting information; comparisons with currently distributed devices; and data showing the effect on safety and effectiveness of any significant changes from the pre-1976 device. *Ibid.*

Once a device has been approved for marketing under Section 510(k), the manufacturer may not market or promote it for uses other than those specified in the FDA clearance.[3] However, physicians remain free under federal law to employ the device for any purpose, including so-called "off-label uses." See *Ortho Pharm. Corp.* v. *Cosprophar, Inc.*, 32 F.3d 690, 692 (2d Cir. 1994). Not only has the FDA recognized the existence of off-label uses (which, as part of the practice of medicine, it cannot regulate, see 21 U.S.C. § 396); it has also acknowledged that "'unapproved' or, more precisely, 'un-labeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches

---

[2] These requirements were expanded by the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990), to require more detailed descriptions of the design, materials, properties, functioning, and scientific basis of the device. See 21 C.F.R. §§ 807.87, 807.92, 807.93 (1998).

[3] What constitutes marketing or promotion remains uncertain. See *Washington Legal Found.* v. *Friedman*, 36 F. Supp. 2d 16, 19 (D.D.C. 1999).

* * * that have been extensively reported in medical literature." FDA DRUG BULL. 12:4-5 (1982) (quoted in 59 Fed. Reg. 59820, 59821 (1994)). Off-label uses of devices have "traditionally been regulated by the hospitals in which the physicians practice and not by the FDA." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993) (quoted in Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 77 (1998)).

B. The FDA's Clearance of the Bone Screws

Petitioner The Buckman Company (Buckman) is a regulatory consultant for medical device manufacturers, helping them navigate FDA procedures, plan regulatory strategy, and monitor clinical trials. In 1984, AcroMed Corporation hired Buckman as its liaison with the FDA to attempt to obtain marketing clearance for its devices. See App., *infra*, 4a-5a.

In September 1984, Buckman, on behalf of AcroMed, applied for Section 510(k) marketing clearance for an orthopedic bone screw device, the Variable Screw Placement Spinal Plate Fixation System (VSP).[4] This application stated that AcroMed intended to market the VSP as a pedicle screw for use in spinal surgery. App., *infra*, 5a. The FDA rejected the application, finding that the VSP was a Class III device not substantially equivalent to any pre-1976 devices. A year later, AcroMed, through Buckman, submitted a second Section 510(k) application for the VSP, again indicating that the device would be labeled as a pedicle screw. The FDA rejected this application as well. *Ibid.*

---

[4] Also at issue is AcroMed's ISOLA Spine Fixation System, for which Buckman obtained Section 510(k) clearance in 1986. Like the Third Circuit, "our discussion of the VSP system applies with equal force to the ISOLA system." App., *infra*, 5a n.2.

In December 1985, following a meeting with FDA officials, AcroMed and Buckman separated the VSP into its component parts — the screw and the plate — and sought Section 510(k) approval for each. App., *infra*, 5a. These applications specified that the devices were intended to be used in the arm and leg long bones, rather than in the spine. The FDA determined that the screw and plate individually were substantially similar to pre-1976 devices and granted the applications in February 1986. *Id.* at 5a.

Despite the limited nature of the FDA clearance, "[i]n practice, surgeons often use[d] orthopedic screws which FDA ha[d] cleared for other purposes * * * as pedicle screws." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993) (quoted in Beck & Azari, 53 FOOD & DRUG L.J., at 77). Indeed, the FDA observed in 1995 that, since at least 1992, pedicle fixation with screws has been "considered to be the standard of care by the surgical community." 60 Fed. Reg. 51946, 51947 (1995). These uses, though widespread, were all off-label, because the FDA did not approve the marketing of bone screws for use in spinal surgery until January 1995. *Id.* at 51947-48.

C. The Orthopedic Bone Screw Product Liability Litigation

As just noted, after AcroMed placed its bone screws on the market, orthopedic surgeons used them, as well as bone screws produced by other manufacturers, as spinal fixation devices. After a national television program ran a story on alleged harm caused by this use of the bone screws, thousands of plaintiffs filed state-law suits against doctors, hospitals, universities, bone screw manufacturers, and regulatory consultants such as Buckman, alleging product defects and fraud in the manufacturers' representations to the FDA. The federal suits — approximately 2,300 civil cases involving 5,041 plaintiffs and 334 defendants — were consolidated in this multidistrict litigation. App., *infra*, 55a.

Plaintiffs did not contend that, in applying for Section 510(k) clearances, Buckman or AcroMed had misrepresented any objective fact, such as the size, shape, or technical characteristics of the screws or their equivalence to pre-1976 devices. Rather, plaintiffs claimed that Buckman and AcroMed deceived the FDA as to the "intended uses" of the devices, representing that they would be labeled for long bones while planning to market them for use in the spine. App., *infra*, 6a. In plaintiffs' view, the Section 510(k) clearances were the product of fraud under state law and, but for such fraud, the devices would never have been on the market and would not have been used in their pedicle surgery.

On March 2, 1995, the district court, relying on *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 516 U.S. 815 (1995), granted judgment on the pleadings on all "fraud on the agency" claims, holding that they were pre-empted both expressly by the MDA and impliedly by the federal scheme, which vests in the FDA exclusive authority to prosecute violations of the MDA. App., *infra*, 46a-53a. The MDA's express preemption provision, the district court explained, simply "does not permit courts to 'perform the same functions initially entrusted to the FDA.'" *Id.* at 49a (quoting *Michael*, 46 F.3d at 1329). Moreover, "[b]ecause the FDA possesses the proper authority to regulate this field, courts are prohibited from conducting 'a searching state inquiry into the inner workings of FDA procedures.'" *Ibid.* (quoting *Michael*, 46 F.3d at 1329); see also *id.* at 50a (reasoning that, "given the FDA's central role in reviewing and approving devices * * * [the agency] is in the best position to decide whether [a manufacturer] withheld material from the agency and, if so, the appropriate sanction"). Finally, the court reasoned that permitting "fraud on the agency" claims would be inconsistent with Congress's failure to authorize a private right of action under the Food, Drug and Cosmetic Act. *Ibid.*

Following this Court's *Medtronic* decision in 1996, plaintiffs sought to revive their "fraud on the FDA" claims and various defendants (including Buckman) moved the district court to reaffirm its prior decision. App., *infra*, 7a, 33a. On March 28, 1997, the district court reaffirmed its ruling. *Id.* at 33a-44a. The court agreed with plaintiffs' argument that *Medtronic* had undercut portions of its previous analysis, but concluded that "fraud on the agency" claims were still precluded because they were inconsistent with Congress's decision not to include a private right of action under federal law. *Id.* at 36a. Such claims, the district court reasoned, are simply "not interchangeable" with the claims at issue in *Medtronic*, which involved no allegation of fraudulent procurement of agency approval and therefore did not amount to a collateral attack on any agency decision. *Id.* at 40a.

Because "fraud on the FDA" was the sole claim against Buckman, the district court granted Buckman's motion for dismissal for failure to state a claim on which relief could be granted (App., *infra*, 45a) and certified the dismissal as a final order under Rule 54(b) of the Federal Rules of Civil Procedure. *Id.* at 54a-56a.

D. The Court of Appeals' Decision

A divided panel of the court of appeals reversed, over a "vehement[]" (App., *infra*, 32a) dissent by Judge Cowen. The majority concluded that *Medtronic*'s construction of the MDA's express preemption clause undermined the holding in *Michael* that state law "fraud on the FDA" claims are expressly and impliedly preempted. *Id.* at 13a-17a. The Third Circuit acknowledged that this holding was in direct conflict with the Seventh Circuit's decision in *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (1997), cert. denied, 118 S. Ct. 1300 (1998), which held that "fraud on the FDA" claims remain preempted after *Medtronic*. App., *infra*, 17a n.5.

The court of appeals rejected Buckman's express and implied preemption arguments. In the majority's view, the

MDA does not expressly preempt "fraud on the FDA" claims because the Section 510(k) process does not establish *any* "federal 'requirement'" that is "'applicable to the device' at issue here." App., *infra*, 13a. In equally sweeping fashion, the majority — adopting the position of a distinct minority of circuit courts — broadly declared that plaintiffs' common law claims do not impose *any* "state 'requirements' 'with respect to' that device." *Ibid.*

The Third Circuit also rejected the argument that "fraud on the agency" claims are impliedly preempted. App., *infra*, 16a. The majority recognized that "Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA." *Id.* at 13a. But it "s[aw] no inconsistency" between Congress's decision to give the FDA the "exclusive prerogative" and discretion to enforce the requirements of federal law and allowing individuals to "bring common law fraudulent misrepresentation claims" to "enforce the FDCA." *Id.* at 18a.

Judge Cowen dissented. Unlike the majority, he was greatly troubled by permitting judges and juries hearing "fraud on the FDA" claims "to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing." App., *infra*, 32a. Judge Cowen observed that "[t]he majority endorses a claim of 'fraud on the FDA' under circumstances that will expose manufacturers to fraud liability for seeking desirable innovations in a product's use, distort the penalty scheme established by the FDCA and its regulations, and generate substantial liability when manufacturers respond to doctors' widely accepted practice of purchasing medical products for off-label uses." *Id.* at 25a.

REASONS FOR GRANTING THE PETITION

The decision below creates one circuit conflict and extends another as to vitally important and frequently recurring issues of federal law: (1) whether "fraud on the agency" claims brought under state law are expressly or impliedly

preempted by a comprehensive federal regulatory regime administered by an expert administrative agency; and (2) whether this Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), exempts from both express and implied preemption *all* state requirements that happen to be imposed through state tort laws of general applicability.

The Third Circuit is the first federal court of appeals to allow plaintiffs to bring tort actions under state law challenging FDA decisions as fraudulently obtained. Prior to *Medtronic,* every circuit to address the issue had held that such claims were preempted by federal law. As the court below acknowledged, its decision also squarely conflicts with a post-*Medtronic* decision of the Seventh Circuit. App., *infra*, 17a n.5. This intercircuit conflict impairs the stability and uniformity of the FDA's decisionmaking process.

Moreover, the circuit split over preemption of "fraud on the agency" claims extends beyond the MDA to cases involving similar regulatory schemes. See *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) (Boat Safety Act preempts "fraud on the agency" claim), cert. dismissed, 118 S. Ct. 1793 (1998); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) "does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), cert. denied, 118 S. Ct. 1839 (1998). Thus, if permitted to stand, the decision below will allow litigants in the Third Circuit to circumvent express preemption provisions in a number of federal statutes.

Review of this case would also allow the Court to resolve widespread uncertainty over the meaning of *Medtronic*. In the wake of *Medtronic*, lower courts have disagreed over whether the MDA preempts only state "requirements" that apply exclusively to medical devices or whether it also preempts some state requirements imposed through laws of

general applicability. See *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1371 n.7 (11th Cir. 1999) (acknowledging conflict). The court below, like the Tenth Circuit, interpreted *Medtronic* as exempting state tort requirements from preemption simply because of their generality, while the Fourth, Sixth, Seventh and Ninth Circuits have rejected that view. Compare *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997), with *Mitchell* v. *Collagen*, 126 F.3d 902, 912 (7th Cir. 1997) (*Mitchell II*), cert. denied, 118 S. Ct. 1300 (1998); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.), cert. denied, 118 S. Ct. 166 (1997); *Martin* v. *Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097-98 (6th Cir. 1997), cert. denied, 118 S. Ct. 850 (1998); and *Duvall* v. *Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996). Because these disputes are attributable to ambiguities in the *Medtronic* decision itself, only this Court can bring clarity to this important area of federal law.

I. The Circuits Are Divided Over Whether "Fraud on the Agency" Claims Are Preempted By Federal Law

A. This Case Squarely Presents the Conflict

The decision below creates a conflict in the circuits over whether "fraud on the agency" claims are preempted under the MDA and other federal statutes containing analogous express preemption clauses. In contrast to the Third Circuit, the Seventh and Eleventh Circuits have held that collateral attacks on agency rulings through private tort actions are expressly and impliedly preempted. See *Mitchell II*, 126 F.3d at 913-14 (MDA preempts "fraud on the FDA" claims); *Lewis*, 107 F.3d at 1502; see also *Kuiper*, 131 F.3d at 666. This split is the result of disagreements over the meaning of *Medtronic*, as a brief review of its development demonstrates.

1. Prior to *Medtronic,* the lower courts were in general agreement that state law claims alleging fraud on the FDA either were expressly preempted by 21 U.S.C. § 360k(a) or were impliedly preempted both because they would interfere

with the FDA's exclusive authority over the regulatory regime for medical devices and because the MDA contains no private cause of action.[5]

Courts reasoned that "fraud on the FDA" claims were expressly preempted because they would impose requirements under state law that were "different from, or in addition to" (21 U.S.C. § 360k(a)) the FDA's clearance requirements under the MDA. See, *e.g.*, *Reeves*, 44 F.3d at 307 ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."); *Michael*, 46 F.3d at 1329 ("Under § 360k, states may not * * * reach a different conclusion than the FDA."); *Mitchell I*, 67 F.3d at 1283 ("[I]f the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a [different or additional] state requirement."). State liability predicated on a manufacturer's failure to make certain disclosures to the FDA also raised the specter that a "manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity." *Talbott*, 63 F.3d at 29.

---

[5] See *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), cert. dismissed, 517 U.S. 1230 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995) (*Mitchell I*), vacated, 518 U.S. 1030 (1996); *Michael*, 46 F.3d at 1328-29; *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), cert. denied, 515 U.S. 1104 (1995); *Mears* v. *Marshall*, 905 P.2d 1154 (Or. Ct. App. 1995), vacated, 921 P.2d 966 (Or. 1996); see also *Scott* v. *CIBA Vision Corp.*, 38 Cal. App. 4th 307 (1995) (preemption of claim of negligence per se for failure to follow FDA regulations). But see *Evraets* v. *Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779 (1994) (no preemption).

Courts had also rejected "fraud on the agency" claims in other regulatory contexts. See *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir.) (FIFRA), cert. denied, 510 U.S. 913 (1993); *Oeffler* v. *Miles, Inc.*, 642 N.Y.S.2d 761, 765 (N.Y. Sup. Ct. 1996) (same); see also *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995) (FIFRA preempts claims that would "allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations"); *Worm* v. *American Cyanimid Co.*, 5 F.3d 744, 748 (4th Cir. 1993) (FIFRA preempts state law claim that manufacturer should have "voluntarily [made] additional disclosures and representations" and sought permission from the EPA to modify its label); *Wegoland Ltd.* v. *Nynex Corp.*, 27 F.3d 17, 21 (2d Cir. 1994) (filed-rate preemption doctrine bars claims of fraud on a rate-setting agency); *Taffert* v. *The Southern Co.*, 967 F.2d 1483, 1488-95 (11th Cir. 1992) (en banc) (same); *H.J., Inc.* v. *Northwestern Bell Tel. Co.*, 954 F.2d 485, 491-92 (8th Cir. 1992) (same).

In addition to express preemption, courts found that state law "fraud on the FDA" claims were impliedly preempted because they would "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995). Such claims would frustrate Congress's desire to create a unitary device marketing clearance system, enforced by the FDA, and would conflict with Congress's determination not to include a private cause of action under the MDA. See *Michael*, 46 F.3d at 1329 ("[P]ermitting a fraud claim based on false representation to the FDA would conflict with our precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act."); *Talbott*, 63 F.3d 29-30 ("Congress * * * has not provided for [private policing of the MDA], choosing instead to place sole enforcement authority in the hands of the FDA.").

2. There matters stood at the time of the Court's decision in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996). In *Medtronic*,

a 4-1-4 decision, the Court addressed negligence and strict liability claims brought against the manufacturer of an allegedly defective pacemaker that had received the FDA's Section 510(k) marketing clearance. Although the Court held that those claims were not expressly preempted, its fractured decision failed to articulate a single interpretation of the MDA preemption provision.

Both the plurality and Justice Breyer, who concurred in part and concurred in the judgment, rejected the argument that Section 360k(a) preempts *all* state law product liability claims relating to a medical device. See 518 U.S. at 487-89 (plurality); *id.* at 503-05 (Breyer, J. concurring). They also agreed that, to preempt state law, the manufacturing, design, and warning requirements imposed on a device by federal law must be "specific." See *id.* at 500; see also *id.* at 506-07 (Breyer, J.). Because the Section 510(k) process did not impose specific design requirements, and because the FDA's regulations did not impose specific warning and manufacturing requirements, the Lohrs' tort claims were not preempted. *Id.* at 493, 501; *id.* at 508 (Breyer, J.). Finally, the Court held unanimously, in dicta, that state law claims seeking to impose identical requirements are not "different from, or in addition to" federal requirements and are thus not preempted. *Id.* at 495 (majority); *id.* at 513 (opinion of O'Connor, J.).

3. Although *Medtronic* did not involve a "fraud on the agency" claim, and the Court's analysis was not broad enough to cover such claims, the unclear opinions have been a source of confusion for lower courts.

After *Medtronic,* the Third Circuit overruled its decision in *Michael* and held that "fraud on the agency" claims are not preempted. App., *infra*, 16a-17a; see also *Mears* v. *Marshall*, 944 P.2d 984, 992 (Or. Ct. App. 1997) (allowing "fraud on the agency" claims on remand after *Medtronic*). The Seventh Circuit, in contrast, reaffirmed its decision in *Mitchell I* and held that *Medtronic* does not save "fraud on the agency"

claims from preemption. See *Mitchell II*, 126 F.3d at 913-14. The division is also reflected in other courts. See *Carey* v. *Shiley, Inc.*, 32 F. Supp. 2d 1093, 1108 (S.D. Iowa 1998) (finding preemption); *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996) (finding no preemption); *Green* v. *Dolsky*, 685 A.2d 110, 117 n.7 (Pa. 1996) (same), cert. denied, 520 U.S. 1168 (1997); *Dutton* v. *AcroMed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997) (same).

Courts finding no preemption have interpreted *Medtronic* as holding that the Section 510(k) process imposes no federal requirements, as opposed to merely no federal *design* requirements (App., *infra*, 13a), and that state law requirements that a manufacturer not defraud the FDA are identical to MDA requirements. See *Mears*, 944 P.2d at 992 n.4; *Connelly*, 927 S.W.2d at 855; *Green*, 685 A.2d at 414 n.7; *Dutton*, 691 N.E.2d at 742. See also *Goodlin*, 167 F.3d at 1375. Courts finding preemption, on the other hand, have held that the MDA approval process imposes federal disclosure requirements and that allegations of "liability under state law despite [the defendant's] conformity to the [FDA] requirements * * * must be considered preempted. Permitting such claims would add requirements that are 'different from, or in addition to,' those established" by the MDA. *Mitchell II*, 126 F.3d at 913-14; see *Carey*, 32 F. Supp. 2d at 1108.

This post-*Medtronic* conflict, moreover, has not been confined to the MDA, but extends to similar regulatory contexts. Compare *Lewis*, 107 F.3d at 1505 ("fraud on the Coast Guard" claim preempted under Federal Boat Safety Act), and *Kuiper*, 131 F.3d at 666 ("FIFRA does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), with *Hoelck* v. *ICI Americas, Inc.*, 584 N.W.2d 52, 61 (Neb. Ct. App.) (FIFRA does not preempt claim "based upon * * * failure to disclose relevant information to the EPA"), review denied (Oct. 28, 1998).

In contrast to the Seventh and Eleventh Circuits, the court below misunderstood the limited effect of *Medtronic* on the previously uniform rejection of "fraud on the agency" claims. Without resolution of the conflict by this Court, lower courts will continue to disagree over whether state juries can sit as "super-[agency] review boards that could question the adequacy of the [agency's] determination of whether a * * * registrant successfully complied with * * * [the agency's] regulations." *Kuiper*, 131 F.3d at 666 (quoting *Welchert* v. *American Cyanamid Inc.*, 59 F.3d 69, 73 (8th Cir. 1995)).

B. The Issue Presented by the Conflict is Recurring and of Great Practical Importance

The conflict in the circuits over "fraud on the agency" claims is particularly significant because of its far-reaching legal and practical effects. To begin with, because the Third Circuit's decision arises out of a multidistrict litigation proceeding involving literally thousands of cases, to which the decision below has already been applied, the opinion obviously has a far more substantial impact than the typical appellate decision in an ordinary product liability case.

Furthermore, "fraud on the agency" claims are not confined to the medical device context but have the potential to undermine a broad range of federal regulatory schemes.[6] "Virtually any federal agency decision that stood in the way of a lawsuit could be challenged indirectly by a claim that the

---

[6] Numerous federal regulatory statutes contain preemption provisions with operative language virtually identical to the MDA. See, *e.g.*, FIFRA, 7 U.S.C. § 136v(b); Flammable Fabrics Act, 15 U.S.C. § 1203(a); Federal Hazardous Substances Act, *id.* § 1261 note (b)(1)(A); National Traffic and Motor Vehicle Safety Act, *id.* § 1392(d); Poison Prevention Packaging Act, *id.* § 1476(a); Consumer Product Safety Act, *id.* § 2075(a); Electronic Product Radiation Control Act, 21 U.S.C. § 360ss; Federal Boat Safety Act, 46 U.S.C. § 4306.

industry involved had misrepresented the relevant data or had otherwise managed to skew the regulatory result." *Lewis*, 107 F.3d at 1505. Under the MDA and analogous federal statutes, "fraud on the agency" claims thus provide a ready means to circumvent almost any preemptive federal requirement.[7] "Congress could not have intended for the process it so carefully put in place" by passing such statutes "to be so easily and thoroughly undermined." *Ibid.*

Even as limited to the MDA, the decision below will have an enormous impact on the medical device industry and on the public health. Allegations of fraud, even if unsubstantiated, may trigger burdensome, intrusive, and expensive discovery into product development files, often covering multi-year periods and evolving scientific evaluations of complex formulas and patient reactions.[8] In the highly competitive medical device industry, companies could bring such claims against manufacturers of successful devices,

---

[7] Indeed, such claims may be brought under state law even where, as here, the agency itself does not believe it was "defrauded." Despite the fact that plaintiffs filed comments with the FDA detailing the allegations of fraud that form the basis of their claims, the FDA granted permission for the bone screws at issue to be labeled for use in spinal fixation. See *In re Orthopedic Bone Screw Prods Liab. Litig.*, 1995 WL 764580, at *5-*6 (E.D. Pa. Dec. 14, 1995); 63 Fed. Reg. 40025 (1998).

[8] These discovery proceedings could embroil the agency in time-consuming and disruptive private litigation, as litigants seek to obtain the best evidence about whether the agency was defrauded and, if so, what the agency would have done in the absence of the fraud. This case provides a compelling example. Petitioner and other defendants submitted strong evidence that the "fraud" alleged by plaintiffs — the submission of separate Section 510(k) applications for the component plates and screws of the AcroMed system — was in fact *suggested by FDA personnel*. See Pet. C.A. Br. at 15-18; Pet. C.A. App. Tab 2, Exhs. 1-2.

asserting that FDA actions were obtained through fraud. The FDA, not the courts, is the appropriate forum for considering such claims, through the agency's established procedures. See, *e.g.*, 21 C.F.R. §§ 10.25, 10.30, 10.33, and 10.35.

What is more, because "fraud on the agency" claims would subject medical device manufacturers to a duty to comply with the shifting and uncertain requirements imposed by juries applying the common law of the 50 states, manufacturers could never be certain that their submissions to the FDA were adequate. They would be compelled to inundate the agency with unnecessary data and speculative impressions in order to foreclose future state law claims that they procured the FDA's clearance through fraudulent concealment. At the same time, manufacturers would be far more reluctant to respond in valid, nonpromotional ways (such as by sending reprints of scientific articles) to physician inquiries concerning off-label uses of their products, for fear that such communications would be taken as evidence of the manufacturer's "true" "intended use" for the device and "fraud on the agency."

Armed with less information, many physicians would make less informed treatment decisions and might also be discouraged from engaging in off-label uses. But, as noted above, the practice of using drugs and medical devices for purposes other than those designated by the manufacturers during the FDA approval process is both extremely common and largely beneficial to patients. See PHYSICIANS' DESK REFERENCE COMPANION GUIDE 1623-54 (1998) (listing common off-label uses for nearly 1000 medical conditions). Indeed, the FDA is well aware of the prevalence and public benefits of such off-label uses. See FDA DRUG BULL. 12:4-5 (1982) (quoted in 59 Fed. Reg. 59820, 59821 (1994)). Given the widespread use of devices for off-label purposes, it is inevitable that manufacturers' submissions to the FDA will vary from the drugs' or devices' eventual uses — a circumstance that renders manufacturers particularly susceptible to the claim that they "defrauded" the federal agency.

Finally, "fraud on the FDA" claims, such as this one, that allege fraud in an "intended use" statement (made before any marketing has taken place) could lead to liability absent proof of *any* actual marketing violations. As a practical matter, however, such claims would "throw[] into the jury box" the difficult, policy-laden question of if and "when unacceptable 'marketing' has taken place" (App., *infra*, 29a (Cowen, J., dissenting)). Congress and the FDA have developed complex statutes and regulations explaining when manufacturers may disseminate information on off-label uses. See 21 U.S.C. §§ 360aaa to 360aaa-6; 63 Fed. Reg. 64556 (1998). If "fraud on the agency" claims are allowed to proceed, "[t]he penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." App., *infra*, 28a (Cowen, J., dissenting). In sum, as Judge Cowen correctly noted, "when juries are permitted to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing, they will fail to provide a consistent standard, inhibit valuable exchange of information on off-label uses, and needlessly raise the price of drugs and medical devices." *Id.* at 32a.

II. The Decision Below Reflects Widespread Uncertainty Over the Meaning of *Medtronic* v. *Lohr*, Which This Court Alone Can Dispel

Wholly apart from its impact on "fraud on the agency" claims, the decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has engendered a sharp conflict in the circuits on a fundamental question of immense importance to the scope of MDA preemption: whether the MDA was intended to preempt state laws of general applicability. See *Goodlin*, 167 F.3d at 1371 n.7 (noting circuit split); *Mitchell II*, 126 F.3d at 913 n.4 (same). Just over a year ago, the Solicitor General acknowledged "the division among the lower courts" on "questions concerning Section 360k's preemption of state common or statutory law applied in tort suits" and recom-

mended that the Court "grant review and definitively resolve the conflict" in an appropriate case. No. 96-1405 U.S. Br. at 18, *Smiths Indus. Med. Sys.* v. *Kernats*.

The confusion in the lower courts is traceable to Justice Breyer's tie-breaking vote in *Medtronic* (see *Mitchell II*, 126 F.3d at 912; *Papike*, 107 F.3d at 742) and to the effect of an FDA regulation interpreting the MDA's express preemption provision, 21 U.S.C. § 360k(a) (preempting state requirements *"with respect to a device"* that are "different from, or in addition to" federal requirements) (emphasis added).[9] The FDA has construed the highlighted language to mean that state requirements are not preempted if they are "requirements of general applicability." See 21 C.F.R. § 808.1(d)(1)

---

[9] The lower courts are in dispute over whether deference is owed to an administrative agency's interpretation of an express preemption clause. See *Commonwealth Edison Co.* v. *Vega*, 1999 WL 212210, at *5 (7th Cir. April 13, 1999) (noting circuit conflict); see also *Massachusetts* v. *United States Dep't of Transp.*, 93 F.3d 890, 894 (D.C. Cir. 1996) (stating that "[n]either the Supreme Court nor this one has ever definitively decided" this issue). Compare *Brannan* v. *United Student Aid Funds*, 94 F.3d 1260, 1263 (9th Cir. 1996) (deferring to agency interpretation), cert. denied, 521 U.S. 1106 (1997), *Gustafson* v. *City of Lake Angelus*, 76 F.3d 778, 786 (6th Cir. 1996) (same), *Time Warner Cable* v. *Doyle*, 66 F.3d 867, 876 (7th Cir. 1995) (same), and *Elizabeth Blackwell Health Ctr. for Women* v. *Knoll*, 61 F.3d 170, 182 (3d Cir. 1995) (same), with *Grunbeck* v. *Dime Svg. Bank*, 74 F.3d 331, 341 (1st Cir. 1996) (refusing to defer to agency interpretation of "bare statutory language" of preemption provision); *Teper* v. *Miller*, 82 F.3d 989, 998 (11th Cir. 1996) (opinion of Kravitch, J.) ("it is not at all clear" that a court should defer to agency views on preemption); *Brannan*, 94 F.3d at 1268 (Fletcher, J., dissenting) (no deference to agency preemption interpretations), *Knoll*, 61 F.3d at 185 (Nygaard, J., dissenting) (same), and *Colorado Public Utilities Comm'n* v. *Harmon*, 951 F.2d 1571, 1579 (10th Cir. 1991) (same).

(no preemption of "State or local requirements of general applicability where the purpose of the requirements relates either to other products in addition to devices * * * or to unfair trade practices in which the requirements are not limited to devices").

The Court's opinion in *Medtronic*, which Justice Breyer joined, agreed that under the FDA's interpretation of the MDA preemption provision, only state requirements that are "specific" are subject to preemption. See 518 U.S. at 500; see also *id.* at 506-07 (Breyer, J.). But the Court also stated: "[W]e do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted * * * ." *Id.* at 500; see also *id.* at 514 (opinion of O'Connor, J.) (noting that "the statutory language does not indicate that a requirement must be specific, either to preempt or to be preempted"). The majority nevertheless held that the tort claims involved in that case "escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." *Id.* at 501 (plurality); *id.* at 508 (Breyer, J.).

In his separate opinion, however, Justice Breyer agreed with the four dissenting Justices who had rejected reliance on the FDA preemption regulation. See 518 U.S. at 503 ("I basically agree with Justice O'Connor's discussion of [whether the MDA will ever preempt a state law tort action] and with her conclusion."); *id.* at 511 (opinion of O'Connor, J.) (concluding that state common law damages actions can be preempted). Justice Breyer also indicated that he disagreed with the plurality "that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare[.]'" *Id.* at 508. And Justice Breyer explained that the state requirements that can be preempted include "a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-05. In fact,

Justice Breyer gave a lengthy explanation of how a state negligence claim, perhaps the paradigmatic general state common law requirement, can be a preempted state "requirement." *Id.* at 504.

Medtronic's inconsistency over whether generalized state tort claims can be preempted under the MDA has played itself out in the circuit courts. The court below and the Tenth Circuit have held that *Medtronic* bars preemption of state law claims of general applicability, citing the part of the plurality opinion that Justice Breyer joined but ignoring the reasoning of his separate concurrence.[10]

On the other hand, the Fourth, Sixth, Seventh and Ninth Circuits have held that the MDA can preempt general common law tort claims.[11] Focusing on the language of

---

[10] See App., *infra*, 12a (general common law "state requirements * * * escape pre-emption * * * because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices") (quoting *Medtronic*, 518 U.S. at 501); *id.* at 13a (the state tort claim of "fraud on the agency" presented no "state 'requirement' 'with respect to'" the bone screws at issue); *Oja*, 111 F.3d at 789 ("Like the * * * claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent * * * claim were not specifically developed 'with respect to' medical devices. * * * Instead, Oja's * * * claim is predicated upon a general duty applicable to every manufacturer * * *.") (citing *Medtronic*, 518 U.S. 501-02).

[11] See *Mitchell II*, 126 F.3d at 912 ("[I]n order to determine whether a common law cause of action is preempted * * * it is necessary * * * to determine whether the *final judgment* of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.") (emphasis added); *Papike*, 107 F.3d at 742 (finding preemption even though "generally applicable state law principles are involved"); *Martin*, 105 F.3d at 1099 (holding that a "generally applicable" negligent manufacturing claim was preempted); *Duvall*, 103 F.3d at 330

Justice Breyer's concurring opinion, these courts have concluded that

> it makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law 'requirements' which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted * * *.

Mitchell II, 126 F.3d at 912 (quoting *Papike*, 107 F.3d at 742). The D.C., First and Eighth Circuits have adopted a similar interpretation of Justice Breyer's *Medtronic* concurrence in cases involving other regulatory statutes.[12]

This disarray is also reflected in the federal district and state courts.[13] Indeed, the conflict is all the more troubling

---

(holding that "common-law causes of action" may be preempted by the MDA).

[12] See *Geier* v. *American Honda Motor Co.*, 166 F.3d 1236, 1240 & n.10 (D.C. Cir. 1999); *Symens* v. *SmithKline Beecham Corp.*, 152 F.3d 1030, 1055 (8th Cir. 1998); *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 554 (1st Cir. 1996), cert. denied, 519 U.S. 1149 (1997).

[13] Compare, *e.g.*, *Easterling* v. *Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 370 (E.D. La. 1997) (allowing preemption of state general common law claims); *Lake* v. *TPLC*, 1 F. Supp. 2d 84, 87 (D. Mass. 1998) (same); *Chmielewski* v. *Stryker Sales Corp.*, 966 F. Supp. 839, 842-43 (D. Minn. 1997) (same); *Richman* v. *W.L. Gore & Assoc.*, 988 F. Supp. 753, 757 (S.D.N.Y. 1997) (same); *Berish* v. *Richards Med. Co.*, 937 F. Supp. 181, 185 (N.D.N.Y. 1996) (same); *Steele* v. *Collagen Corp.*, 54 Cal. App.4th 1474, 1486-87 (1998) (same); *Hernandez* v. *Coopervision, Inc.*, 691 So.2d 639 (Fla. Dist. Ct. App. 1997) (same); *Weiland* v. *Telectronics Pacing Sys., Inc.*, 704 N.E.2d 854, 861 (Ill. App. Ct. 1998) (same), appeal allowed (Ill. Mar. 31, 1999) (Table, No.

because in eight states (California, Kentucky, Illinois, Michigan, Ohio, Oregon, Pennsylvania, and Washington), state appellate court decisions on MDA preemption of tort claims directly contradict those of the relevant federal court of appeals.[14] Resolution of such conflicts is essential to

---

86903); *Connelly*, 927 S.W.2d at 854-55 (same); *Sowell* v. *Bausch & Lomb, Inc.*, 230 A.D.2d 77, 83-4 (N.Y. App. Div. 1997) (same); *Green*, 685 A.2d 110 (same); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511 (R.I.) (same), cert. denied, 118 S. Ct. 374 (1997); *Worthy* v. *Collagen*, 967 S.W.2d 360, 371 (Tex. 1998) (same); with *Lakie* v. *SmithKline Beecham*, 965 F. Supp. 49, 53-54 (D.D.C. 1997) (general common law claims not preempted because of generality); *Armstrong* v. *Optical Radiation Corp.*, 50 Cal. App.4th 580 (1996) (same); *Kernats* v. *Smiths Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct. 1996) (same), cert. denied, 118 S. Ct. 684 (1998); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 822-23 (Ky. 1997) (same), cert. denied, 118 S. Ct. 1187 (1998); *Walker* v. *Johnson & Johnson Vision Prods, Inc.*, 552 N.W.2d 679, 686 (Mich. Ct. App. 1996) (same); *Baird* v. *American Med. Optics*, 713 A.2d 1019, 1029-30 (N.J. 1998) (same); *Dutton*, 691 N.E.2d at 741-42 (same); *Mears*, 944 P.2d at 990 (same); *Wutzke* v. *Schwaegler*, 940 P.2d 1386, 1389-90 (Wash. Ct. App. 1997) (same), review denied, 953 P.2d 96 (Wash. 1998).

[14] Compare App., *infra*, 12a-13a (3d Cir.) (not allowing preemption), with *Green*, 685 A.2d 110 (Pa.) (allowing preemption); *Papike*, 107 F.3d at 741 (9th Cir.) (allowing preemption), with *Mears*, 944 P.2d at 990 (Ore.) (not allowing preemption), 50 Cal. App.4th 580 (Cal. Ct. App) (same), and *Wutzke*, 940 P.2d at 1389-1390 (Was. Ct. App.) (same); *Mitchell II*, 126 F.3d at 913 (7th Cir.) (allowing preemption) with *Kernats*, 669 N.W.2d 1300 (Ill. App. Ct.) (not allowing preemption); *Martin*, 105 F.3d at 1997-98 (6th Cir.) (allowing preemption), with *Walker*, 552 N.W.2d at 686 (Mich. Ct. App.) (not allowing preemption), *Niehoff*, 950 S.W.2d at 822-23 (Ky.) (same), and *Dutton*, 691 N.E.2d at 741-42 (Ohio Ct. App.) (same).

prevent forum shopping. See *Baldwin* v. *Alabama*, 472 U.S. 372, 374 (1985).

Because the scope of preemption varies widely among the circuits, medical device manufacturers, which do business in all 50 states, confront dramatic differences in liability exposure from state to state for the identical products. And because the conflict stems from ambiguities in this Court's decision in *Medtronic*, additional litigation in the lower courts is most unlikely to lead to further clarity. Without a definitive resolution, the MDA, designed to promote uniform regulation of life-saving medical devices, will instead continue to spawn inconsistent rulings.

III. The Decision Below Is Incorrect

A. The Court Below Erred In Concluding That "Fraud on the Agency" Claims Are Not Subject To Preemption Under *Medtronic*

There is no sound reason to suffer the harms discussed above because the Third Circuit's decision is incorrect. The court below arrived at the counterintuitive conclusion that the MDA does not preempt "fraud on the agency" claims by repeatedly misconstruing this Court's precedents.

1. *Medtronic* restated the general principles of an express preemption inquiry: courts should consider whether the case falls "in a field which the States have traditionally occupied," 518 U.S. at 485, as well as the "purpose of Congress" and the "structure and purpose of the statute as a whole." *Id.* at 485-86. The Third Circuit applied none of these factors, all of which counsel in favor of preemption of "fraud on the agency" claims. For example, unlike the product liability suit at issue in *Medtronic*, this case involves the accuracy of submissions *to a federal agency*, a field that the states have *never* occupied. Similarly, unlike the product liability suit in *Medtronic*, preempting plaintiffs' claims would not have the "effect of granting complete immunity from design defect

liability to an entire industry." *Id.* at 487. To the contrary, plaintiffs would still be able to bring personal injury suits against the manufacturers, as well as fraud claims for representations made to them or their physicians. Put another way, preemption here would not eliminate any claim that plaintiffs would have had under state law if the MDA had not been enacted.

Finally, the "structure and purpose of the statute as a whole" suggest preemption. The MDA and its accompanying regulations contemplate a unified federal approach to marketing clearance of medical devices, giving the FDA discretionary power both to require additional information from applicants (21 C.F.R. §§ 807.87(*l*), 807.92(d)) and to punish false statements in applications through rescinding approval, requiring corrective actions, or ordering a recall (see, *e.g.*, 21 U.S.C. §§ 331q(2), 336, 337(a); *Talbott*, 63 F.3d at 29; 56 Fed. Reg. 46191, 46200 (1991)).

2. Even when it understood *Medtronic*'s approach to MDA express preemption, the Third Circuit misapplied those principles. In particular, the court below erroneously applied the holding of five Justices in *Medtronic* that only "specific" federal requirements can preempt state laws that impose requirements "different from" or "in addition to" the federal requirements. See 518 U.S. at 500 (plurality); *id.* at 506-07 (Breyer, J.).

The Third Circuit transformed this Court's determination that the Section 510(k) process imposes *no federal design requirements* into a holding that the Section 510(k) process imposes *no federal "requirements" at all*. Compare 518 U.S. at 493-94 (rejecting preemption of design claim because the Section 510(k) process did not "'require' Medtronic's pacemaker to take any particular form for any particular reason") with App., *infra*, 12a ("The § 510(k) process * * * established no federal requirement 'applicable to a device' within the meaning of the MDA."). Given the detailed and

specific regulatory requirements of the Section 510(k) approval process (see 21 C.F.R. § 807.87), this leap of logic is simply indefensible.[15] In essence, the Third Circuit attempted to deny the existence of the very federal requirements that plaintiffs accused Buckman of violating.

The final misstep in the Third Circuit's express preemption analysis was its holding that "fraud on the agency" claims are not "different from, or in addition to" the Section 510(k) requirements. But to prevail on their fraud claim, plaintiffs would have to prove that Buckman was required to disclose its plans to violate wholly separate FDA marketing regulations in its Section 510(k) application. Federal law imposes no such disclosure requirements. Under the MDA, "intended use" is determined by "the objective intent of the persons legally responsible for the labeling of devices" (21 C.F.R. § 801.4); see also 21 U.S.C. § 360c(i)(1)(E)(i); 21 C.F.R. § 807.87(e)), not by the applicant's subjective expectations. As Judge Cowen observed, the majority "stretches the 'intended use' statement" into both a statement of subjective intent and "an all purpose guarantee that an applicant will not violate other FDA rules." App., *infra*, 27a. State law claims that would impose liability for failing to disclose information that the FDA itself does not require are certainly "different from" and "in addition to" the federal requirements and are preempted by Section 360k(a).

3. All else aside, it should be clear that *Medtronic* had no effect on implied preemption principles. This Court was explicit that even common law claims can still be "preempted under conflict pre-emption analysis." 518 U.S. at 503; see

---

[15] For example, the Section 510(k) process requires that devices be "substantially equivalent" to pre-1976 devices in order to obtain marketing clearance. See 21 U.S.C. § 360e(b)(1)(B). Surely a state law that instead required a medical device to be "exactly identical" to a pre-1976 device would be preempted.

also *id.* at 507-08 (Breyer, J.). For this reason alone, the Third Circuit erred in holding that *Medtronic* undermined prior decisions holding that "fraud on the agency" claims were impliedly preempted.

As previously explained, plaintiffs' suit would require juries applying state law to determine what information should have been submitted to the FDA and whether the agency, if it had received that information, would have reached a different result on AcroMed's Section 510(k) application. Claims such as this would plainly frustrate the MDA's purpose of having uniform federal submission requirements and vesting all authority over medical device marketing in the FDA. See *Michael*, 46 F.3d at 1329; *Mitchell I*, 67 F.3d at 1283. As the Eleventh Circuit explained, "[r]egulatory fraud claims" are

> impliedly preempted for fundamental, systemic reasons. Permitting such claims would allow juries to second-guess federal agency regulators * * *. If that were permitted, federal regulatory decisions that Congress intended to be dispositive would merely be the first round of decision making, with later more important rounds to be played out in the various state courts.

Lewis, 107 F.3d at 1505.

Indeed, the conflict between "fraud on the agency" claims and the FDA's regulatory procedures is most stark in cases, such as this one, where the FDA has been presented with the very same evidence of "fraud" and determined that the device is properly on the market. See note 7, *supra*. Plaintiffs' claim, pure and simple, is that the FDA should not have granted Section 510(k) approval to the bone screws and should instead have required the more exacting premarket approval process. But the FDA, fully aware of plaintiffs' position, has only recently reiterated that "premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness." 63 Fed. Reg. 40025,

40032 (1998). The FDA has gone so far as to reclassify the bone screws, deciding that pedicle fixation should be a labeled use for many of the devices and spinal conditions involved in this litigation. *Ibid.*

The essence of plaintiffs' state law claim is that the medical devices at issue "had no lawful access to the market for any purpose." App., *infra*, 23a. Yet, the FDA, applying federal law, has repeatedly concluded that the devices should be on the market. Plaintiffs' suit would "stand[] as an obstacle" to the accomplishment of that federal purpose. *Freightliner*, 514 U.S. at 287.

B. The Court Below Erred In Holding That State Tort Claims Are Not Preempted Because of Their Generality

The Third Circuit's conclusion that state tort law requirements are not preempted because of their generality contradicts the holding in *Medtronic*, the text of the preemption provision, and common sense.

As the Fourth, Sixth, Seventh and Ninth Circuits have recognized, common law tort claims can be preempted under the MDA. See pages 19-23, *supra*. This also was the view of five Justices in *Medtronic*, who stated that the MDA can preempt "a standard of care or behavior imposed by a state-law tort action." 518 U.S. at 504-05 (Breyer, J.); see also *id.* at 510-12 (opinion of O'Connor, J.).

Indeed, in *Medtronic*, the FDA's own lawyer — the Solicitor General — rejected the proposition on which the Third Circuit rested its holding: the phrase "with respect to" in Section 360k(a) means that common law claims are never preempted. The Solicitor General stated (Br. 17): "The Lohrs argue that the 'with respect to' phrase limits the scope of the provision to state requirements that *specifically refer or relate to medical devices*, and therefore excludes *general* common-law duties. *That argument is strained as a grammatical*

matter." (citation omitted and emphasis added). In fact, the Solicitor General maintained, exactly the opposite is true: "[T]he 'with respect to' clause *suggests that such a 'requirement' may be one of general applicability.*" *Id.* at 18 (emphasis added). The Solicitor General went on to argue that common law duties qualified as "requirements" within the meaning of Section 360k(a). *Id.* at 15-19, 25 n.20.

The Third Circuit's position lacks any support in the text of the MDA. The language of Section 360k(a) broadly preempts "any" state requirement that affects "a device intended for human use," is "different from, or in addition to" any federal requirement, and "relates to" either "the safety or effectiveness of the device" or "any other matter included in a requirement applicable to the device under [the MDA]." 21 U.S.C. § 360k(a). Only a strained interpretation of these deliberately broad phrases can sustain the Third Circuit's determination that Section 360k(a) bars preemption of generally applicable tort requirements even when they are applied in the specific context of medical devices.

Finally, a blanket exclusion of generally applicable state tort claims would be nonsensical. There is no reason to believe that Congress cared about the form, as opposed to the content, of state requirements applicable to medical devices or intended to allow the states to avoid preemption through creative legislative drafting. As this Court has recognized in other preemption settings, recognition of a broad exception for "generally applicable" state requirements would create "an utterly irrational loophole." *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992); accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959). The same is true here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

SCOTT BURESH
FRED FELLER
Buresh, Kaplan, Jang, Feller & Austin
2298 Durant Ave.
Berkeley, CA 94704
(510) 548-7474

KENNETH S. GELLER
Counsel of Record
ALAN E. UNTEREINER
Mayer, Brown & Platt
1909 K Street, N.W.
Washington, DC 20006
(202) 263-3000

GEORGE P. NOEL
Noel & Hackett
P.O. Box 1590
Media, PA 19063
(610) 892-7700

Counsel for Petitioner

MAY 1999

APPENDICES

APPENDIX A

In re ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION,

Plaintiffs Legal Committee, Appellant.

No. 97-1783.

United States Court of Appeals, Third Circuit.

Argued June 9, 1998.

Decided Nov. 17, 1998.

Before: STAPLETON, COWEN and RENDELL, Circuit Judges.

OPINION OF THE COURT

STAPLETON, Circuit Judge:

This case involves thousands of individual plaintiffs-appellants who claim that they suffered injuries resulting from the implantation of orthopedic bone screws into the pedicles of their spines. Over 2,000 individual actions were consolidated for pre-trial proceedings pursuant to the multi-district litigation statute, 28 U.S.C. § 1407. This appeal involves plaintiffs' allegations that one defendant, Buckman Company, Inc. ("Buckman"), made misrepresentations to the Food and Drug Administration ("FDA") serious enough to play a substantial role in the events which resulted in their injuries. The district court granted Buckman's motion to dismiss this state-law "fraud on the FDA" claim, determining that: (1) the claim was "precluded by virtue of the fact that the MDA [i.e., the Medical Device Amendments of 1976, 21 U.S.C. §§ 360c-360k, to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301 et seq.] does not provide for a private right of action," App. at 157;

and (2) plaintiffs could not, as a matter of law, demonstrate proximate causation between the misrepresentations to the FDA and any injuries suffered. App. at 158-59. We will reverse.

I.

A.

The orthopedic bone screw devices that are the subject of this suit are regulated by the FDA pursuant to the MDA. Congress enacted the MDA to address concerns regarding the safety and effectiveness of the wide variety of medical devices introduced into the market. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996). The MDA requires classification of medical devices into three categories based upon the risk that they pose to the public. Class I devices present no unreasonable risk of illness or injury and are subject only to general manufacturing controls. See 21 U.S.C. § 360c(a)(1)(A). Class II devices are potentially more harmful and are subject to federal performance regulations. See *id.* § 360c(a)(1)(B). Finally, Class III devices "present[ ] a potential unreasonable risk of illness or injury" and are subject to the strictest regulation. *Id.* § 360c(a)(1)(C).

Class III devices may not be introduced into the market until the manufacturer provides the FDA with "reasonable assurance" that the device is both safe and effective. See *id.* § 360e(d)(2). This "premarket approval" process requires a manufacturer to submit, and the FDA to review, "all information, published or known ... or which should reasonably be known ... concerning investigations which have been made to show whether or not such device is safe and effective." *Id.* § 360e(c)(1)(A). In addition, the manufacturer must provide the FDA with a full statement of design and manufacturing plans, as well as any additional information requested by the agency. See *id.* § 360e(c)(1). Securing premarket approval is an arduous and time-

consuming process; each submission requires an average of 1,200 hours of FDA review. See *Lohr*, 518 U.S. at 477, 116 S. Ct. 2240.

There are three important exceptions to the requirement that Class III medical devices receive premarket approval before being placed on the market. First, a manufacturer can obtain an Investigational Device Exemption ("IDE"), which allows limited use of an experimental medical device to gather the type of data necessary to support a premarket approval application. See 21 U.S.C. § 360j(g). Though an IDE allows use of a Class III device in clinical trials, it does not permit introduction to the general public.

Second, the MDA allows Class III devices that were in commerce prior to its enactment to remain on the market until the FDA initiates and completes a premarket approval analysis for those "predicate" devices. See *id.* § 360e(b)(1)(A). This "grandfathering" provision reflects Congress' recognition "that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices." *Lohr*, 518 U.S. at 477-78, 116 S. Ct. 2240.

Third, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices wait for FDA approval, and to ensure that improvements to existing devices are introduced quickly, the MDA allows devices that are "substantially equivalent" to an existing predicate device to avoid the premarket approval process. See *Lohr*, 518 U.S. at 478, 116 S. Ct. 2240; 21 U.S.C. § 360e(b)(1)(B). The procedure a manufacturer follows to take advantage of this exception is known colloquially as the "§ 510(k) process," after the number of the relevant section in the original Act. A § 510(k) application must contain information supporting the device's substantial equivalence to a predicate device, proposed labeling for the device, and any additional information requested by the FDA. See 21 C.F.R. § 807.87.

For a device to be approved under the § 510(k) process, the FDA must determine that the new device has the same intended use as the predicate device and that it possesses the same technological characteristics or is as safe and effective as the predicate device. See 21 U.S.C. § 360c(i)(1)(A).[1] The advantage of the § 510(k) process is significant to manufacturers: review of a § 510(k) application by the FDA requires an average of only twenty hours of agency time, compared to the 1,200 hours required for full premarket approval. See *Lohr*, 518 U.S. at 478-79, 116 S. Ct. 2240.

B.

Buckman is a regulatory consultant to medical device manufacturers, and was retained by the AcroMed Corporation to act as its liaison to the FDA in its attempt to secure marketing clearance for its product. AcroMed initiated the § 510(k) process to secure marketing clearance for its orthopedic bone screw device, known as the Variable Screw Placement ("VSP") Spinal Plate Fixation System, in September 1984.[2] In this application, AcroMed indicated that

---

[1] A device is "substantially equivalent" to a predicate device if it:

> (i) has the same technological characteristics as the predicate device, or
>
> (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary ..., that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

21 U.S.C. § 360c(i)(1)(A).

[2] A second device, known as the ISOLA Spine Fixation System, is also at issue in this appeal. Since the facts alleged regarding both

it intended to market the device for use in spinal surgery. The FDA rejected the request, determining that the VSP device was a Class III device and was not substantially equivalent to any predicate device.

In September 1985, AcroMed, through Buckman, filed a second application for marketing clearance through the § 510(k) process. The application provided additional information about the VSP device and again indicated its intended use in spinal surgery. The FDA again rejected the application, determining that the device was not substantially equivalent to a predicate device and that it posed potential risks not exhibited by other spinal-fixation systems.

In December 1985, AcroMed and Buckman filed two final § 510(k) applications seeking market approval for its product. AcroMed and Buckman split the VSP device into its component parts, renamed them "nested bone plates" and "cancellous bone screws" and filed a separate § 510(k) application for each component. In both applications, a new intended use was specified: rather than seeking clearance for spinal applications, they sought clearance to market the plates and screws for use in the long bones of the arms and legs. AcroMed and Buckman claimed that the two components were substantially equivalent to predicate devices used in long bone surgery. The FDA approved the devices for this purpose in February 1986.

The subject of this appeal is plaintiffs' fraud on the FDA claim against Buckman. Plaintiffs allege that AcroMed, through Buckman, made material misrepresentations in its successful § 510(k) submission to the FDA. Specifically, plaintiffs allege that AcroMed, through Buckman, "sought approval of its VSP plates and screws for use in long bones simply as a pretext in order to market the device for its true

---

systems are substantively similar, our discussion of the VSP system applies with equal force to the ISOLA system.

intended use in the spine." App. at 58. According to the plaintiffs, Buckman, AcroMed and other defendants contrived a strategy in which they would (1) misrepresent the intended use of the screw system to the FDA, (2) obtain the FDA's approval to market the system for that misrepresented use, and (3) subsequently market the system for a use, spinal surgery, for which they could not obtain the FDA's approval. Plaintiffs contend that, as a result of the mis-representations to the FDA, a § 510(k) clearance was issued, allowing the devices access to the market they would not otherwise have had.

C.

In 1994, the Judicial Panel on Multidistrict Litigation designated the district court as the transferee court for *In re: Orthopedic Bone Screw Liability Litigation*, MDL No. 1014. Since that time, some 2,300 civil actions have been transferred to the district court. In March 1995 the district court granted a motion brought by AcroMed and other defendants to dismiss plaintiffs' fraud on the FDA claims, determining that those claims (1) were preempted by the MDA, and (2) impermissibly implied a private right of action for violation of the FDCA. See App. at 28 (Pretrial Order No. 12). Relying on our decision in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.1995), the district court's order purported to "dismiss[ ] all fraud on the FDA ... claims contained in any pleading" in the consolidated litigation. App. at 37.

Subsequently, in June 1996, the Supreme Court decided *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996), in which the Court addressed the scope of MDA preemption for the first time. As a result of that decision, plaintiffs filed amended complaints which re-asserted fraud on the FDA claims against Buckman and other defendants. AcroMed and other defendants filed a motion to reaffirm Pretrial Order No. 12 in light of *Lohr*. Buckman

joined this motion, but also simultaneously filed its own motion to dismiss the fraud on the FDA claims against it. The district court granted AcroMed's motion and reaffirmed Pretrial Order No. 12, though on modified grounds. The district court recognized that *Lohr* likely invalidated one of the two grounds for its prior decision. Nevertheless, it concluded that *Lohr* did not completely undermine Pretrial Order No. 12 because *Lohr* "did not address claims of fraud on the FDA with respect to the absence of a private right of action for violations of the FDCA." App. at 157. The district court determined that allowing a fraud on the FDA claim would essentially create a private right of action for violation of the FDCA and that, "in view of the FDA's exclusive prosecutorial discretion ... any grant of an implied private right of action would be contrary to the letter and spirit of the statute." App. at 153.

In addition, the district court determined that dismissal of plaintiffs' fraud on the FDA claims was warranted because "the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries." App. at 158. The court reasoned that since any misrepresentations were directed only to the FDA and any injuries were caused only by unrelated physicians, the connection between the alleged fraud and plaintiffs' injuries "is so tenuous, if existent at all, that the former cannot be said to be a 'substantial factor' in causing the latter." App. at 159 (citations omitted).

After granting AcroMed's motion to dismiss the fraud on the FDA claims, the district court subsequently granted Buckman's identical motion to dismiss "for the reasons stated in Pretrial Order No. 845." App. at 162 (Pretrial Order No. 900). Thereafter, the district court certified Pretrial Order

No. 900 as a final order pursuant to Fed.R.Civ.P. 54(b). See App. at 163 (Pretrial Order No. 1067).[3]

We have jurisdiction over the final order of the district court pursuant to 28 U.S.C. § 1291. We exercise plenary review over a dismissal for failure to state a claim, and we accept all factual allegations of the plaintiffs as true and draw all reasonable inferences therefrom in their favor. See *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc.*, 140 F.3d 478, 483 (3d Cir. 1998).

II.

Count I of the complaint tendered to us as representative is entitled "Fraud (on the FDA)." App. at 55. It alleges that: (1) "[i]n response to the FDA's inquiry concerning the intended use of the bone plates and bone screws, ... Buckman, acting as representative of AcroMed ... intentionally and falsely represented to the FDA that ... [they were] 'intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones,'" App. at 58; (2) "Buckman ... intended for the FDA to clear the VSP device components based upon this misrepresentation," *id.*; (3) "[i]n reliance on this express misrepresentation, the FDA determined ... that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed ... prior to May 28, 1976 for the intended use represented by AcroMed" and issued a § 510(k) clearance, id.; (4) "the VSP device was intended exclusively for use in the spine," *id.*; (5) "the only

[3] Certification was proper for Pretrial Order No. 900 because plaintiffs asserted no other claims against Buckman other than the fraud on the FDA claims. As a result, Buckman is the only proper party to this appeal. Although Sofamor, S.N.C. and Danek Medical, Inc. submitted a joint brief and an appendix as appellees, we treated those documents as submissions of amici curiae and issued an appropriate order to that effect.

purpose for which AcroMed's plates and screws were sold was for use in the spine," *id.*; (6) "[t]he FDA was ignorant of the fact that these devices and device components were intended by AcroMed to be used as pedicle screw fixation devices," *id.* at 63; (7) "[w]ere it not for these fraudulent acts and statements, the FDA would not have issued § 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff's spine," *id.*; and (8) "[a]s a direct and proximate result of the wrongful conduct alleged in Count I of this Complaint, Plaintiff has suffered, and will continue to suffer, severe physical harm, including injury to Plaintiff's spine," *id.* at 63-64.

Count I is thus drafted to track the elements of a common law cause of action for fraudulent misrepresentation: (1) a representation of fact, opinion, intention or law; (2) knowledge of its falsity; (3) an intent to induce reliance; (4) justifiable reliance; and (5) resulting injury. See *Restatement (Second) of Torts* § 525 *et seq.*

At the time of the decision here appealed, the bone screw cases were still at the pleading stage. While it is clear that the plaintiffs' "fraud on the FDA" claims are based on state rather than federal law, neither the parties nor the district court have yet addressed the potential choice of law issues and those issues are not before us. We note at the outset, however, that the controlling state law of fraudulent representation in some cases may be different from that in other cases. This is important to our analysis because the district court's dismissal of all "fraud on the FDA" claims was appropriate only if federal law forecloses resort to state law or if the allegations comprising those claims do not state a claim on which relief can be granted under any of the potentially applicable state laws. We first address the issue of whether federal law forecloses resort to state law and then

turn to the issue of whether the allegations of the complaints may state a claim under any of the potentially applicable state laws.

III.

A.

The MDA contains the following preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.[4]

The FDA regulations interpreting § 360k of the MDA provide in part as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted

[4] Subsection (b) of § 360k grants authority to the Secretary of Health and Human Services to grant exemptions from preemption and is not pertinent here.

> ... because they are not "requirements applicable to a device" within the meaning of section [360k] of the act. The following are examples ...:
>
> (1) Section [360k] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.
>
> (2) Section [360k] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996), the Supreme Court applied these statutory and regulatory provisions in the context of a suit against the manufacturer of a pacemaker that had been cleared as a Class III device under § 510(k). Lohr, the plaintiff there, asserted common law negligence and strict liability claims based on the design of the pacemaker as well as state law claims based on defective manufacture and mislabeling. The Court held that these claims were not preempted.

The Court gave the preemption provision of the statute a narrow reading. It stressed that preemption occurs under § 360k only when (1) there is a state "requirement" "with respect to a device;" (2) there is a federal "requirement" "applicable to the device" under the MDA; (3) the state requirement is "different from, or in addition to" the federal requirement; and (4) the state requirement relates to the safety or effectiveness of the device or some matter included in the federal requirement. See 518 U.S. at 500, 116 S. Ct. 2240.

The Court found that issuance of a § 510(k) clearance "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the MDA process." 518 U.S. at 483-84, 116 S. Ct. 2240. The § 510(k) process thus established no federal requirement "applicable to a device" within the meaning of the MDA. "Similarly, the general state common law requirements [relied upon by Lohr] were not specifically developed 'with respect to' medical devices. Accordingly, they [were] not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.* at 501, 116 S. Ct. 2240. The general obligations imposed by the state common law relied upon by Lohr were "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Id.* at 501-02, 116 S. Ct. 2240.

The Court also held that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.... The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.* at 495, 116 S. Ct. 2240.

B.

Based on *Lohr*, it is apparent that, within the meaning of § 360k, there is no federal "requirement" "applicable to the device" at issue here; nor is there a state "requirement" "with respect to" that device. Moreover, the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law. As plaintiffs stress, 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful.

C.

Neither the district court nor Buckman takes issue with any of these conclusions concerning the effect of *Lohr* on the "fraud on the FDA" claims in this suit. The district court expressly acknowledged that *Lohr* was inconsistent with one of the two grounds it originally articulated for dismissing these claims. It nevertheless concluded that *Lohr* was consistent with dismissal because its alternative ground remained unaffected by *Lohr*. As the district court put it, "[w]hile Lohr may have affected the portion of [the court's prior decision] that relied on the doctrine of preemption, the portion of the court's reasoning based on the absence of an implied right of action [under the FDCA] remains in tact." App. at 152-53. We disagree.

It is, indeed, well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA. It is also true, as the district court pointed out, that this court, in *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995), found this fact significant in the course of holding that a common law fraud claim against the manufacturer of a heart valve was preempted by the FDCA. We there concluded:

Under § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA. "[W]here the FDA was authorized to render the expert decision ..., it, and not some jury or judge, is best suited to determine the factual issues and what their effect could have been on its original conclusions." *King* [*v. Collagen Corp.*, 983 F.2d 1130,] 1140 [(1st Cir. 1993)] (Aldrich & Campbell, J.J. concurring). Under the MDA, states have no authority to police Shiley's compliance with the FDA's procedures. If Shiley knowingly misled the FDA in its PMA application, it is for the FDA to remedy that situation using the authority Congress gave it in the MDA.

Further, permitting a fraud claim based on false representations to the FDA would conflict with our precedent that plaintiffs not bring implied causes of action for violations of the *Food, Drug and Cosmetic Act*. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), cert. denied, 513 U.S. 965, 115 S. Ct. 429, 130 L.Ed.2d 342 (1994). Plaintiffs cannot circumvent this bar by characterizing their cause as a claim for state law fraud.

Michael, 46 F.3d at 1329. As we have noted, the district court recognized that the first reason we gave for our holding in *Michael* is untenable after *Lohr*. Nevertheless, it believed that it remained bound by our alternative rationale.

It is important to note at the outset that, contrary to the district court's suggestion, our alternative rationale in *Michael*, like our primary one, was necessarily based on the doctrine of preemption. Absent preemption by federal law (or a ground for stay or abstention, doctrines not pertinent here), a district court having jurisdiction of the parties and the subject matter cannot decline to enforce liability imposed by the relevant state common law. *See, e.g., Polselli v. Nationwide Mutual Fire Insurance Co.*, 126 F.3d 524, 527

n.1 (3d Cir. 1997) ("A federal court exercising diversity jurisdiction must apply the substantive law of the state whose laws govern the action."). *Cf. Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S. Ct. 817, 82 L.Ed. 1188 (1938) ("Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the State."). This is important to understand because " '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Lohr*, 518 U.S. at 485, 116 S. Ct. 2240 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103, 84 S. Ct. 219, 11 L.Ed.2d 179 (1963)). Unless Congress intends preemption, there is none. Accordingly, where Congress has expressed itself on preemption in a statute, "Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Id.* at 486, 116 S. Ct. 2240 (quoting *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 111, 112 S. Ct. 2374, 120 L.Ed.2d 73 (1992) (Kennedy, J., concurring)).

In *Michael*, we inferred from the fact that Congress created no private right of action for violations of the FDCA that it intended to foreclose suits based on state common law that would provide a remedy for conduct violative of that act. Ironically, a plurality of the Supreme Court in *Lohr* drew a diametrically opposed inference from the same fact. It viewed Congress' failure to provide a federal remedy as persuasive evidence of an intent not to preempt common law liability for the same conduct:

> Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons

> injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use," 90 Stat. 539 (preamble to Act). It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S. Ct. 615, 78 L.Ed.2d 443 (1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

Lohr, 518 U.S. at 487, 116 S. Ct. 2240 (footnote omitted) (plurality).

More fundamentally, however, *Lohr* teaches that where Congress has expressed its intention with respect to preemption, we should look primarily to what it said. When it looked to what Congress said in § 360k, the Supreme Court in *Lohr* concluded that Congress did not intend to prevent a state from providing "a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495, 116 S. Ct. 2240.

Refusing to entertain Buckman's fraudulent misrepresentation claim solely because the statutory scheme does not contain a private cause of action would be the equivalent of finding preemption of state law claims contrary to the clear holding of *Lohr*. In short, *Lohr* overrules everything in *Michael* that would prevent a plaintiff from

pursuing a cause of action for fraudulent misrepresentation based on common law principles.[5]

D.

Buckman advances a number of preemption arguments in addition to the one adopted by the district court. In each instance, we conclude that *Lohr* counsels rejection.

Buckman argues that *Lohr* is distinguishable (1) because it "did not involve claims turning on FDA *procedures*, but rather claims that the product itself was defective," Buckman Br. at 12, and (2) because the target of the alleged fraud here is "a creature of statute" which has the sole responsibility for enforcing the FDCA and the regulation promulgated thereunder. Buckman Br. at 10.[6]

---

[5] We respectfully disagree in this regard with the conclusion reached by the Court of Appeals for the Seventh Circuit in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir.1997). It there concluded that our holding in *Michael* survives *Lohr*. 126 F.3d at 914. While it did not explain its conclusion, one can infer from its earlier decision in the same case, 67 F.3d 1268, that it believes the first rationale for our decision in Michael retains vitality.

[6] Buckman and amici (in support of a similar argument) make specific reference to 21 U.S.C. § 337(a) and § 336. Section 337(a) provides:

> Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

Section 336 provides:

> Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution ... minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

Once again, we look first to Congress' express message concerning preemption — § 360k. In the context of the text of that section as construed in *Lohr*, Buckman's suggested distinctions are simply unpersuasive. Indeed, given that there must be state and federal requirements *with respect to a device*, it is harder to argue preemption under § 360k based on FDA procedures than based on FDA substantive requirements for a regulated device.

We do not rule out the possibility that there may be some areas of preemption outside the scope of § 360k based on clear and direct conflicts between the requirements of state law and those of the FDCA. The existence of § 360k, its relatively narrow scope, and *Lohr*'s presumption against preemption of areas traditionally occupied by state law, however, counsel caution in finding implied preemption where no express preemption exists. Here, appellees' argument boils down to a contention that the litigation of suits of this kind is fundamentally inconsistent with the regulatory process established by the FDCA. We see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA and preserving the right of people in the plaintiffs' position to bring common law fraudulent misrepresentation claims. Moreover, we do not share appellees' apparent perception that litigation of such claims holds the potential for courts and juries second-guessing the FDA. Indeed, there is ample precedent, in related contexts, to support a claim premised on misrepresentations made to a federal agency. *See, e.g., Learjet Corp. v. Spenlinhauer*, 901 F.2d 198, 202-03 (1st Cir. 1990) (allowing aircraft purchaser's claim against manufacturer based on misrepresentation to Federal Aviation Administration); *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 F.2d 553, 568-69 (3d Cir. 1983) (allowing patient's claims against drug manufacturer based on misleading the FDA); *Hawkins v. Upjohn Co.*, 890 F.Supp. 609, 612 (E.D. Tex. 1994) (same).

IV.

Buckman also asks us to affirm on the alternative ground that the complaints do not state a claim for fraudulent misrepresentation. Three reasons for such a conclusion are urged. First, it is said that the complaints do not, and cannot, allege causation. Second, it is argued that, in the context of a § 510(k) application, a statement of the intended purpose of the applicant, as a matter of law, is not a representation of fact, opinion, or intention. Finally, it is argued that the complaints do not, and cannot, allege reliance by the plaintiffs on the alleged misrepresentation by the FDA.

A.

The district court determined that plaintiffs' fraud on the FDA claims should be dismissed because "the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries." App. at 158. In the court's view, "[l]egal causation largely fails because the object of plaintiffs' fraud-on-the-FDA claim is the FDA and not the doctors who performed surgeries on the plaintiffs or the plaintiffs themselves. ... The causal connection between the alleged fraud committed on the FDA and plaintiffs' alleged injuries is so tenuous, if existent at all, that the former cannot be said to be a 'substantial factor' in causing the latter." App. at 158-59. While we are not in a position to canvass all the potentially applicable law, what we know about tort law generally makes us unwilling to say that all of the plaintiffs' claims will fail for want of the kind of a causation that will give rise to liability.

First, the mere fact that the alleged fraudulent misrepresentation was made to the FDA and not the plaintiffs does not necessarily preclude a finding of legally sufficient causation. Section 310 of the *Restatement (Second) of Torts* states, for example:

> An actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by ... a third person in reliance upon the truth of the representation, if the actor
>
> (a) intends his statement to induce or should realize that it is likely to induce action by ... a third person, which involves an unreasonable risk of physical harm to the other, and
>
> (b) knows
>
> (i) that the statement is false, or
>
> (ii) that he has not the knowledge which he professes.

Another example is provided by our decision in *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 F.2d 553 (3d Cir.1983). The plaintiff there, who had suffered brain damage as the result of an adverse reaction to the local anesthetic, Xylocaine, recovered a substantial judgment against the manufacturer of the drug. The plaintiff alleged that the defendant had misled the FDA by withholding information it was required to report concerning adverse effects previously suffered by others. We sustained the judgment against an attack that there was no legally sufficient causal connection between the defendant's misleading conduct and the plaintiff's injury. We concluded:

> The jury heard the testimony of four well qualified expert witnesses ... from which they could infer ... (1) that had the FDA had these reports, it would have required notice to the medical community (through the package insert or PDR) of the critical information contained in the more than 200 adverse-reaction reports of the incidence of cardiac and respiratory arrest, notwithstanding low dosage of Xylocaine; and (2) that physicians receiving this information would have considered it in deciding how—and whether—to

> administer Xylocaine to their patients. Resolving every inference in plaintiffs' favor, we cannot conclude that the record was devoid of the requisite minimum quantum of evidence supporting the verdict.

718 F.2d at 569 (footnote omitted).

We have earlier reviewed the specific allegations of the representative complaint in this matter regarding causation. Plaintiffs' theory is that, without Buckman's fraudulent representation, the FDA would not have given AcroMed a § 510(k) clearance and that, absent a § 510(k) clearance, AcroMed would not have access to the market to promote its devices for use in spinal surgery and plaintiffs would not have suffered injury. Given the terminology chosen, it appears to us that the district court viewed the causation standard for unintentional torts as the applicable one and regarded the yielding of plaintiffs' physicians to AcroMed's promotion as an intervening cause. It may be that plaintiffs' theory would be so viewed under the law of some jurisdictions. It is not clear to us, however, that it would be so viewed under all of the potentially applicable law. Buckman's representation to the FDA regarding intended use is alleged to have been intentional. Moreover, while it is not alleged that harm to plaintiffs was intended, plaintiffs do claim to be able to show that Buckman's representation was a necessary element of a conspiracy to get doctors to do exactly what plaintiffs' physicians did. *See, e.g., Restatement (Second) of Torts* § 435 B ("Unintended Consequences of Intentional Invasions") and § 442 B ("Intervening Force Causing Same Harm as That Risked by Actor's Conduct").

We do not hold that plaintiffs have or have not alleged a legally sufficient causal nexus. That issue can be resolved only after the controlling law has been identified in each case. We do hold that the district court erred in determining at this stage that all of the plaintiffs have failed to allege a legally sufficient causal nexus.

B.

Buckman insists that a statement of intended use in connection with a § 510(k) application is not a representation of a fact or intent but, rather, a request for authority. In its view, the sole interest of the FDA in the applicant's intended use is to enable it to limit the authority granted to that which is sought and considered by the agency. In a related argument, Buckman contends that FDA reliance on the alleged misrepresentation is "negated in this case by ... the nature of the clearances that were given to AcroMed," Buckman Br. at 23, i.e., they were limited to long bone use only.

We, of course, acknowledge that a statement of intended use in connection with a § 510(k) application has utility in communicating the authority sought and in permitting the FDA to appropriately limit any authority granted. At the same time, we believe that such a statement is a representation of fact that is necessarily important to the FDA as such.

The use to which a device will be put is of critical importance in the regulatory scheme. A device that presents no risk of injury when employed for one purpose may present great risk of injury when employed for another. For this reason a § 510(k) clearance will be issued only if a device is a substantial equivalent of a preexisting device used for the same purpose. Moreover, a device cleared under § 510(k) cannot lawfully be marketed for a use other than the use specified in the clearance. Thus, if such a device is marketed for another purpose, the manufacturer may be civilly and criminally sanctioned and the marketing enjoined. *See* 21 U.S.C. §§ 331, 332.

According to Buckman, the FDA requires no representation from a § 510(k) applicant regarding its marketing intentions and reads its representation with respect to "intended use" as no more than a description of the

authority sought. Implicit in this view is the assertion that the marketing plans of a manufacturer seeking access to the market are of no interest to the FDA. If this be taken as an assertion of fact by Buckman, it is inappropriate at this stage because it conflicts with the allegations of the complaint. Plaintiff Donald G. Patterson, for example, alleges that "Were it not for [the misrepresentations that the applicant's intended use was in repairing fractures of the long bones], the FDA would not have issued 510(k) clearances ... for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff's spine." App. at 63.

To the extent Buckman's argument is an assertion of law, we find no basis for it in the statute, in the regulations, or in any of the authorities cited in the briefing. To the contrary, such an assumption is fundamentally at odds with the statutory scheme. Under that scheme, the FDA is a gatekeeper charged with the responsibility of protecting the public from unreasonable risks of injury from medical devices. A manufacturer of a new device has no access to the market for any purpose absent some kind of FDA approval. Because the degree of risk presented by any device is a function of the use to which it is put, the intended use is thus a central focus in the FDA review. Indeed, there is nothing more material to its determination of whether to grant access to the market.

It is undoubtedly true, as Buckman insists, that a manufacturer unable lawfully to secure a § 510(k) clearance for one purpose may legally be entitled to a § 510(k) clearance for the same device when put to a different purpose. The allegation here, however, is that AcroMed had no lawful access to the market for any purpose and that it secured such access only by representing that it intended to market its device for one use when, in fact, it intended at the time of the application to market that device solely for

another, more hazardous use.[7] If a manufacturer in AcroMed's position is successful in its scheme, we know that, when its marketing campaign is detected postissuance, the FDA is entitled to an injunction stopping that campaign. Under Buckman's view of the law, however, if the FDA is astute enough to uncover the scheme during its review, it is powerless to deny access to the market in the first place. We decline to accept a proposition so fundamentally at odds with the agency's gatekeeping assignment.

C.

Finally, Buckman argues that on the facts alleged there was no reliance by the plaintiffs on Buckman's statement to the FDA concerning intended use. This is true. This does not, however, negate the possible existence of a claim upon which relief can be granted. As we have earlier noted, § 310 of the *Restatement (Second) of Torts* suggests that when someone makes a fraudulent misrepresentation for the purpose of inducing action by A which, if taken by A, will involve an unreasonable risk of injury to B, B may recover for resulting physical injury even though he was unaware of the fraudulent misrepresentation. It is possible that the controlling law in one or more of these cases takes a similar approach.

V.

Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon

---

[7] The situation here alleged bears no resemblance to one in which an applicant for a § 510(k) clearance intends to market its device for the use represented, subsequently markets for that use, and, at the same time, responds to direct requests for information from physicians concerning off-label use. As a result, we do not share our dissenting colleague's concern that recognizing a statement of intended use in an application for § 510(k) clearance as a representation of the applicant's marketing intentions will chill the dissemination of information relevant to off-label use.

which relief could be granted.[8] Neither we nor the district court is in a position to do that before identifying, with the help of the parties, the governing law or laws. Rather, we hold that (1) the plaintiffs' "fraud on the FDA" theory of liability is not so at odds with traditional principles of tort law that Buckman is entitled to a dismissal of all claims against it at this stage; and (2) if the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be preempted by the MDA. The judgment of the district court will be reversed, and the case will be remanded for further proceedings consistent with this opinion.

COWEN, Circuit Judge, dissenting.

The majority endorses a claim of "fraud on the FDA" under circumstances that will expose manufacturers to fraud liability for seeking desirable innovations in a product's use, distort the penalty scheme established by the FDCA and its regulations, and generate substantial liability when manufacturers respond to doctors' widely accepted practice of purchasing medical products for off-label uses.

To appreciate how much this case departs from previous cases involving "fraud on the FDA," it is important to see what all agree is not fraud in this case. When Buckman sought approval from the FDA for using its screws on long bones, Buckman did not present any false evidence about the similarity of the screws to the already approved long bone screws, and there is no dispute that AcroMed's screws are

---

[8] Nor do we hold, as suggested by the dissent, that any of the plaintiffs have stated a claim under the FDA's regulations. Plaintiffs do not purport to state such a claim and, as we have earlier explained, controlling precedent bars recognition of a private cause of action under the FDCA, the MDA, or their implementing regulations.

"substantially equivalent" to the pre-existing screws. The FDA's determination that AcroMed's screws should be approved for long-bone use has never been questioned.

The basis for the majority's conclusion that Buckman committed fraud on the FDA is that in seeking long-bone approval AcroMed and Buckman really intended to market the screws for spinal use. That is, once the screws could be sold legally for long-bone use, AcroMed planned surreptitiously to induce physicians to buy the screws for spinal use. Clearly, if AcroMed actively marketed the screws for spinal use in violation of FDA's limited approval for long-bone use, AcroMed (and Buckman to the extent it participated in the plan) would have violated the FDA's marketing rule and could be held accountable *by the FDA*. A violation of the marketing rules, however, is not fraud on the FDA; it is an ordinary transgression of an agency's regulatory rules. AcroMed and Buckman also could be held liable by doctors and, in most states, their patients if AcroMed and Buckman told doctors that the bone screws were approved by the FDA for spinal use or made other material misrepresentations. But the statements made to doctors are not the basis for the majority's theory of "fraud on the FDA." To the contrary, the majority finds fraud in Buckman and AcroMed's statement to the FDA of the intended purpose of the screws in their application for long-bone approval. It is on this point that the majority creates dangerous confusion.

The mere fact that AcroMed or Buckman really wanted approval for the spinal use of the screws does not make their request for long-bone approval fraudulent. Seeking approval for one use should not preclude a manufacturer, via the penalty of fraud liability, from seeking approval for another use for the same product. Expanding the uses for existing products will often be a very desirable source of progress and innovation in medical products. A manufacturer may even deliberately start off by seeking approval for a conventional

use while waiting to gain approval for a different, novel and potentially highly profitable use of the product. Such a strategy could have the beneficial effect of increasing competition in the market for the conventional use while at the same time providing revenue to make it easier to negotiate the arduous FDA approval process. By reading the phrase "intended use" in the application as a declaration of what the manufacturer wants ultimately to seek with the medical device, rather than simply as a request for a specific FDA approval (with nothing implied about future requests), the majority creates an interpretation that is economically unrealistic and is likely to hinder technological growth.

The legal concept that the FDA was "defrauded" because a company desired approval for a different use from the one requested and ultimately approved is particularly hard to sustain in this case. Before the FDA approved the screws for long bones, it had twice previously rejected Buckman and AcroMed's applications for spinal use. Those prior applications made unmistakably clear to the FDA that Buckman and AcroMed wanted as their first choice approval for spinal use of the screws. There was no deception about AcroMed's ultimate goals. The FDA most assuredly knew what clearance was sought and what clearance was granted or denied.

The majority may believe that what distinguishes this case from one where a company simply seeks approval for one use while really wanting approval for another (and hence what prevents this decision from flatly prohibiting innovation), is that Buckman and AcroMed obtained long bone approval allegedly with the intention of illegally marketing the screws for off-label use. Such a theory, however, stretches the "intended use" statement into an all purpose guarantee that an applicant will not violate other FDA rules. Under the majority's position the only basis for finding that AcroMed and Buckman committed fraud on the FDA is that they allegedly intended to violate the FDA's

regulations prohibiting marketing for off-label uses. It is hard to see why that is not in effect creating a private right of action for a violation of the FDA regulation, and it is difficult to reconcile that conclusion with a point the majority itself made in footnote 8: "controlling precedent bars recognition of a private cause of action under the FDCA, the MDA, or their implementing regulations." Given the demanding detail of the regulatory process, and the wide variety of violations ranging from the innocuous to the serious, recognizing a state cause of action for violations of FDA regulations will greatly distort the penalty scheme established by the statute. The penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion.

The majority's position is problematic in another closely related respect. The FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products (uses not indicated on the label or approved by the FDA). See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 72 (1998).[1]

---

[1] The article explains that: "It is an accepted principle that once [the] FDA determines that a drug or device can be marketed, a physician's discretionary use of that product (the practice of medicine) is not restricted to the uses indicated on FDA-regulated labels. Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethic[ists], [the] FDA, and most court recognize." BECK & AZARI, *supra*, at 72. The article points out that the FDA stated in a 1982 *Drug Bulletin* that: " 'unapproved' or more precisely 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature... Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations ..."

Doctors may, in the exercise of their professional judgment, decide that based on current medical research an unapproved use of a product best serves a patient's needs.

Permitting off-label uses may seem anomalous given that the FDA's labeling and marketing restrictions prevent companies from actively pursuing an off-label market. Moreover, the fact that the FDA lacks authority to regulate the practice of medicine might imply that off-label uses amount to an end-run around the agency's authority. But the FDA's own position on off-label use reveals that off-label uses are a valuable part of the practice of medicine.[2] The difficulty not confronted by the majority is that there is a very real tension created between endorsing off-label uses but preventing marketing for those uses. Close questions will be raised about whether a manufacturer was simply responding to doctors' desirable demand for off-label uses, or whether a manufacturer was impermissibly trying to create an off-label market and circumvent the FDA's regulation. As matters stood before this decision, the FDA was left to police the boundary between permissible and impermissible responses to off-label demand. The majority's theory, however, now throws into the jury box the question of when unacceptable "marketing" has taken place.

BECK & AZARI, supra, at 77. With regard to bone screws in particular, the article quotes the following statement by the FDA in a 1993 publication titled *Food and Drug Administration, Update on Pedicle Screws:* "In practice, surgeons often use orthopedic screws which FDA has cleared for other purposes ... as pedicle screws. Such use of medical devices for non-approved purposes has traditionally been regulated by the hospitals in which the physicians practice and not by the FDA." BECK AND AZARI, *supra*, at 77.

[2] *See Washington Legal Foundation v. Kessler*, 880 F.Supp. 26, 28 n.1 (D.D.C. 1995), *Washington Legal Foundation v. Friedman*, No. 94-1306, 1998 WL 456372, at *3 (D.D.C. July 30, 1998) and *supra* note 1.

Consider the problem of deciding when impermissible "marketing" has taken place in manufacturer-sponsored continuing medical education ("CME"). After manufacturers began in recent years financially underwriting more CME seminars and materials, the FDA developed, in response to Congressional hearings and ensuing confusion over an FDA concept paper, a twelve-factor test to decide when a manufacturer-sponsored CME seminar violated the FDA's rules on marketing. *See Washington Legal Foundation v. Friedman*, No. 94-1306, 1998 WL 456372, *4 (D.D.C. July 30, 1998) (FDA unconstitutionally restricted commercial speech because less restrictive means of achieving the government's interest were available). As is illustrated by both the complexity of the FDA's test and its efforts to hone its response, difficult and subtle balancing is called for in evaluating manufacturers' roles in the creation and distribution of information about off-label uses of drugs and medical devices.[3] The problem is not easily dismissed. Once

[3] Recent legislation which, once effective, will supersede the FDA's restriction on distributing printed material underscores the incongruity of the majority's position. The Food and Drug Modernization Act of 1997, Pub.L. No. 105-115, 111 Stat. 2296 (to be codified at 21 U.S.C. § 360aaa, et seq.) permits manufacturers to distribute information about off-label uses of drugs and devices provided certain requirements are met. Among the requirements for a drug, for instance, is that the manufacturer must have submitted an application for approval of the new, off-label use. Thus, manufacturers are allowed to submit applications for new uses and to distribute certain information about the off-label use while an application for the off-label use is still pending. On the majority's theory, will the manufacturer have committed fraud on the FDA, notwithstanding the new statutory provisions, if the manufacturer secures approval for one use, distributes materials on off-label uses in compliance with the statute, and does so while its primary objective is to obtain approval for the off-label use pending with the FDA?

it is accepted that off-label uses are desirable, it is difficult to maintain that doctors should be shielded from truthful information concerning when and how to use a product for an off-label use. Patients will benefit by having their doctors informed about off-label uses.

Contrary to the majority's position, the problem of allowing juries to determine when a manufacturer has improperly advertised an off-label use is not only that it will impose too stringent a rule, chilling dissemination of valuable information about off-label uses; it is also that jury decisions lack the consistency of an agency-enforced rule. Even apart from the harm of restricting beneficial information about off-label uses, and the need for a consistently enforced rule wherever the line is drawn, a jury's assessment of liability is problematic in a third sense: Massive liability will be imposed where the FDA would not find any misconduct, and the cost of medical devices will be needlessly raised.

It begs the question simply to respond, as the majority does in footnote 7, that a manufacturer will not face liability when it actually markets for the "intended use" listed in the 510(k) application and answers requests for information about off-label uses. The problem remains: the majority permits liability for fraud on the FDA when a jury concludes that a manufacturer conducted impermissible marketing, demonstrating that the manufacturer "defrauded" the FDA in its statement of intended purpose. Presumably, the majority's response is not that juries' interpretations of "marketing" will pose limited problems because a manufacturer can insulate itself from liability for fraud on the FDA by the simple act of making sales for the intended use listed in the 510(k) application. That seems like a very wooden distinction, for why should those sales be so important from the standpoint of liability for fraud on the FDA? Isn't the problem illegal marketing? If the majority does not require any showing of illegal marketing, how can liability be justified? The effect of the rule will be to prohibit manufacturers from making

otherwise entirely legal responses to demand for off-label uses, responses that the FDA itself accepts as desirable. Or even worse, the rule will very directly prohibit innovation in the uses of drugs and devices by triggering fraud liability when an application is filed for approval of a new use. Once it is admitted that the majority's theory focuses on illegal marketing, we are thrown back on all the problems listed above.

Nowhere does the majority demonstrate the need for its new theory of fraud on the FDA. The plaintiffs can be adequately compensated by their doctors under existing law for any malpractice demonstrated; the defendants can be held liable for fraud if they told doctors they had FDA approval that they did not; and the FDA remains free to prosecute when it feels impermissible marketing has taken place. Manufacturers also can be held liable under product liability law.

In sum, when juries are permitted to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing, they will fail to provide a consistent standard, inhibit valuable exchange of information on off-label uses, and needlessly raise the price of drugs and medical devices. It seems very unlikely that Congress intended a state cause of action to intrude so much both in the enforcement of the FDCA's regulatory scheme and in the severity of the penalties attached to a violation.

I most respectfully, but vehemently, dissent.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

MEMORANDUM AND ORDER

BECHTLE, J. MARCH 28, 1997

Presently before the court is the Sofamor-Danek Defendants' ("defendants") Motion to Reaffirm PTO 12 in Light of *Medtronic, Inc. v. Lohr* and, Alternatively, for Summary Judgment Against Claims Alleging Fraud an the FDA[1] ("Motion to Reaffirm PTO 12") and plaintiffs' response thereto.[2] For the reasons set forth below, the court will grant the motion inasmuch as the reasoning of Pretrial

---

[1] "FDA" refers to the Food and Drug Administration.

[2] On February 6, 1997, defendants withdrew without prejudice the portion of their motion requesting summary judgment. Accordingly, the court will address only the portion requesting reaffirmation of Pretrial Order No. 12's dismissal of plaintiffs' fraud-on-the-FDA claims.

Order No. 12 rests on the absence of an implied private right of action for violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") and deny the motion inasmuch as the reasoning of Pretrial Order No. 12 rests on the doctrine of preemption. Also before the court is defendant Advanced Spine Fixation Systems, Inc. *et al.*'s (also "defendants")[3] Motion to Dismiss Fraud on the FDA, Intracompany Conspiracy, and Liability *per se* Claims Made in Amended Omni Complaints ("Motion to Dismiss")[4] and plaintiffs' response thereto. For the reasons set forth below, the court will grant the portion of the motion requesting the dismissal of plaintiffs, fraud-on-the-FDA claim. The remaining claims for which defendants seek dismissal will be addressed in a separate Memorandum and Order.

I. BACKGROUND

On March 2, 1995, this court entered an Order dismissing plaintiffs' fraud-on-the-FDA claims stating, among other things, that those claims were preempted by the Medical Device Amendments of 1976 ("MDA"), which amended the FDCA. *See* Pretrial Order No. 12 at 4. On June 26, 1996, the United States Supreme Court rendered its decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), holding that the MDA does not preempt a state common-law negligence action against the manufacturer of an allegedly defective medical device. Defendants now seek to have this court reaffirm Pretrial Order No. 12 in light of *Lohr*.

---

[3] The other moving defendants are Robert Howland, Leon Wiltse, M.D., Curtis Spencer III, M.D., and James Thomas, Jr., M.D.

[4] Defendants' Form of Order refers to the motion as "Motion to Dismiss Fraud on the FDA, Intracompany Conspiracy, Fraudulent Marketing and Promotion, and Liability *per se* Claims Made in Amended Omni Complaints." However, the memorandum in support of the motion does not address fraudulent marketing and promotion.

II. DISCUSSION

The court recognizes that it has a "strong duty to decide a case on nonconstitutional grounds whenever possible," *Williams v. School Dist. of Bethlehem*, 998 F.2d 168, 176 (3d Cir. 1993), *cert. denied*, 510 U.S. 1043 (1994), and that "as a matter of established federal jurisprudence ... a court faced with both constitutional and nonconstitutional claims must address the nonconstitutional claims first, if doing so will enable the court to avoid a constitutional confrontation." *Erie Telecomms., Inc., v. City of Erie*, 853 F.2d 1084, 1092-93 (3d Cir. 1988). However, because the motion before the court requests reaffirmation of Pretrial Order No. 12 in light of *Lohr*, and because the court's reasoning in Pretrial Order No. 12 did partly rest on the doctrine of preemption, the court will address the effect of the *Lohr* decision on this court's dismissal of plaintiffs' fraud-on-the-FDA claims on both constitutional and nonconstitutional grounds.

A. Motion to Reaffirm PTO 12

Plaintiffs argue that an FDA regulation and a federal statute requiring truthfulness may serve as the standard of care in a state common-law claim and cite a number of cases in support of this proposition. Plaintiffs point to two provisions which they believe should serve as the standard of care in their state common-law claims — 21 C.F.R. § 807.87(j),[5] which requires that each premarket notification

---

[5] 21 C.F.R. § 807.87 provides in pertinent part:

> Each premarket notification submission shall contain the following information: ...
>
> (j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

submission contain a statement that the submitter believes the premarket notification to be truthful, and 18 U.S.C. § 1001,[6] which makes it a crime to make fraudulent statements to government agencies. Plaintiffs seek to hold defendants liable for violations of these two provisions. Plaintiffs at the same time assert that their fraud-on-the-FDA claim does not invoke the doctrine of negligence per se, although most of their brief argues in favor of this. (Pls.' Mem. Opp'n at 53.) Regardless, the issue before the court is whether *Lohr* now allows plaintiffs' fraud-on-the-FDA claim to go forth. The court holds that it does not. While *Lohr* may have affected the portion of Pretrial Order No. 12 that relied on the doctrine of preemption, the portion of the court's reasoning based on the absence of an implied private right of action remains in tact.

1. Private Right of Action

In Pretrial Order No. 12, the court was primarily guided by *Michael v. Shiley*, 46 F.3d 1316, 1329 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), in which the Third Circuit squarely held that a private party's fraud-on-the-FDA claim would not lie. The *Michael* court reasoned that "permitting a fraud claim based upon false representations to the FDA would conflict with (Third Circuit) precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug, and Cosmetic Act." *Michael*, 46 F.3d at 1329;

---

[6] 18 U.S.C. § 1001 provides:

> Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined under this title or imprisoned not more than five years, or both.

accord Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Sandoz Pharms. Corp. v. Richardson-Vicks., Inc.*, 902 F.2d 222, 231 (3d Cir. 1990). Indeed, in view of the FDA's exclusive prosecutorial discretion under 28 U.S.C. § 337(a), any grant of an implied private right of action would be contrary to the letter and spirit of the statute.[7] *See Lohr*, 116 S. Ct. at 2251 (four-justice plurality) (stating "there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action"). Other circuits also conclude that no private right of action for violations of the FDCA exists. *See, e.g., Bailey v. Johnson*, 48 F.3d 965, 966-68 (6th Cir. 1995); *Rodriguez v. SK&F Co.*, 833 F.2d 8, 9 (1st Cir. 1987); *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976); *see also Griffin v. Medtronic, Inc.*, 82 F.3d 79, 83 n.4 (4th Cir. 1996) ("Of course, Griffin[']s claim might also be premised on the notion that Medtronic did not adequately comply with FDA disclosure requirements. However, the FDA alone is empowered to enforce its regulations. A private right of action seeking enforcement of FDA regulations has not been recognized."), *vacated*, No. 96-603, 1997 WL 63815 (U.S. Feb. 18, 1997).[8]

---

[7] Section 337(a) provides, in pertinent part:

> Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. § 337(a).

[8] In *Griffin*, plaintiff brought five counts against Medtronic, Inc., the manufacturer of plaintiff's failed pacemakers:

(1) negligent design and manufacture;

(2) breach of express warranty;

At least one trial court, however, does not agree. In *Hawkins v. Upjohn Co.*, 890 F. Supp. 609 (E.D. Tex. 1994), the Eastern District of Texas held that under Texas law plaintiffs, conspiracy-to-commit-fraud-on-the-FDA claim stated a claim upon which relief could be granted. *Hawkins*, 890 F. Supp. at 611-12. The *Hawkins* court reasoned that plaintiffs' claim was not based on a violation of the FDCA, but was a common-law fraud claim, and therefore the fact that the FDCA did not create a private right of action was irrelevant. *Id.* at 611. Clearly, the Third Circuit when it decided *Michael*, which post-dated *Hawkins*, was not bound or persuaded by the *Hawkins* decision and neither is this court now. To give credence to the *Hawkins* holding would be to

---

(3) breach of implied warranty of fitness for a particular purpose;

(4) strict liability for defective manufacture; and

(5) intentional misrepresentation of the defective condition of the pacemakers.

Griffin, 62 F.3d at 81. The trial court held that all of plaintiff's claims were preempted. *Id.* The Court of Appeals for the Fourth Circuit affirmed the trial court's ruling on plaintiff's claims of breach of implied warranty, strict liability, negligence, and intentional misrepresentation, and remanded plaintiff's express warranty claim. *Id.* at 83. The Supreme Court vacated the Fourth Circuit's decision stating:

> The judgment is vacated and the case is remanded to the United States Court of Appeals for the Fourth Circuit for further consideration in light of *Medtronic, Inc. v. Lohr* ....

Griffin, 1997 WL 63815. Because the intentional misrepresentation claim actually considered by the *Griffin* court was based on defendant's alleged failure to disclose information to plaintiff and her doctor as opposed to the FDA, the Supreme Court's ruling in *Griffin* does not affect the court's reasoning as to the instant plaintiffs' fraud-on-the-FDA claims.

allow a plaintiff who was clever enough to craft his or her complaint to plead a state common-law cause of action based on alleged wrongs committed against a federal agency to create a private right of action where one did not exist. It appears that in *Hawkins*, the dispositive factor should not have been whether plaintiffs relied on a federal statute to pursue their state common-law claim of conspiracy to commit fraud on the FDA, but rather the fact that the object of the alleged fraud was the FDA, a federal agency with exclusive prosecutorial discretion.

In support of their position, plaintiffs argue that because there are pre-*Lohr* cases which have allowed a violation of the FDCA to establish negligence per se or to establish a rebuttable resumption of negligence, that their fraud-on-the-FDA claim should lie. Plaintiffs cite *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) and *Stanton v. Astra Pharm. Prods. Inc.*, 718 F.2d 553 (3d Cir. 1983) for the proposition that a finding of negligence may be premised on a manufacturer's FDA-created duties not to misbrand products or submit reports of all unexpected adverse reactions to a drug to the FDA. However, these cases are distinguishable from the instant one.

In these two cases where a finding of negligence was premised on a violation of an FDA regulation, the regulation in question was one whose very purpose was to ensure safety. When the FDA explicitly prohibits misbranding or explicitly requires the resorting of adverse reactions to a drug, it is directly regulating public safety; it is pursuing the goals for which it was created, which is to ensure public safety, not to ensure the absence of fraud against it. *See Lohr*, 116 S. Ct. at 2245 (quoting the MDA's preamble and stating that Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use"). The tangential and albeit necessary "requirement" or "duty" or "standard of care" that one be truthful to a government agency, does not emanate from the purpose of the FDCA; it

need not be measured against a regulation prohibiting it. Hence, to label the regulations that plaintiffs cite as the "standard of care" in order to establish a cause of action for fraud on the FDA is ineffective.

2. Preemption

In addition, plaintiffs argue that *Lohr* effectively nullifies the court's ruling in Pretrial Order No. 12. This is only partially correct. While as a general matter *Lohr* established that very few state common-law causes of action are preempted by the MDA, thus invalidating the court's reliance on the doctrine of preemption as a basis for its dismissal of plaintiffs' fraud-on-the-FDA claim, it did not address claims of fraud on the FDA with respect to the absence of a private right of action for violations of the FDCA, which is one of the primary operative impediments to the instant claim's survival.

Lohr held that the MDA does not preempt a state common law negligence action against the manufacturer of an allegedly defective medical device. In the instant case, plaintiffs' fraud-on-the-FDA claim is not interchangeable with the Lohrs' negligence claim. This is so not because a state common-law fraud claim is preempted by the MDA, but because the fraud claim at issue here has as its object the FDA and not plaintiffs. That object transforms an otherwise simple fraud claim that would not be preempted by the MDA according to the reasoning of Lohr into one that is precluded by virtue of the fact that the MDA does not provide for a private right of action. Hence, *Lohr* established that the doctrine of preemption would be an inappropriate ground upon which the court should dismiss plaintiffs' fraud-on-the-FDA claim, but it did not otherwise alter the court's ruling in Pretrial Order No. 12.

B. Motion to Dismiss

Well apart from the questions of whether plaintiffs' fraud-on-the-FDA claim may go forward as an implied private right of action or whether the claim survives preemption, in isolation plaintiffs' claim is not colorable in that it does not pass Federal Rule of Civil Procedure 12(b)(6) muster. Taking all well-pleaded allegations as true and construing the complaint in the light most favorable to the plaintiffs, the court finds that under no reasonable reading of the pleadings, are plaintiffs entitled to relief for the alleged fraud committed on the FDA because the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries. *See Colburn v. Upper Darby Township*, 838 F.2d 663, 665-66 (3d Cir. 1988), *cert. denied*, 489 U.S. 1065 (1989). Legal causation largely fails because the object of plaintiffs' fraud-on-the-FDA claim is the FDA and not the doctors who performed the surgeries on plaintiffs or plaintiffs themselves. Plaintiffs allege that defendants' fraud caused the FDA to issue its 510(k) clearance[9] for the bone screws in question, which allowed the screws to be introduced into interstate commerce, which allowed doctors to exercise their judgment and implant them in plaintiffs' spines, which allowed some plaintiffs to suffer injury. The causal connection between the alleged fraud committed on the FDA and plaintiffs' alleged injuries is so tenuous, if existent at all, that the former can not be said to be a "substantial factor" in causing the latter. *Stanton*, 718 F.2d at 565; *Edward J. DeBartolo Corp. v. Coopers & Lybrand*, 928 F. Supp. 557,

---

[9] "510(k) clearance" refers to the FDA's determination that the bone screws in question are "substantially equivalent" to a bone screw that was commercially distributed before the enactment of the MDA and therefore need not receive premarket approval from the FDA prior to being marketed or sold. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360c(f)(3), 360c(i)(1)(A), 360e; 21 C.F.R. § 807.81 - 807.100.

563 (W.D. Pa. 1996); Restatement (Second) of Torts § 431. Thus, because "it appears beyond doubt" that plaintiffs "can prove no set of facts in support of [their] claim which would entitle [the]m to relief," even if *Lohr* theoretically would allow a private right of action for a fraud-on-the-FDA type of claim to go forward contrary to *Michael*, the court would still be compelled to dismiss it. *See Conley v. Gibson*, 355 U.S. 41, 45 (1957).

III. CONCLUSION

For the reasons stated above, the court will grant in part and deny in part Sofamor-Danek defendants' motion to Reaffirm PTO 12 and grant in part defendant Advanced Spine Fixation Systems, Inc. *et al.*'s Motion to Dismiss.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

PRETRIAL ORDER NO. 845

AND NOW, TO WIT, this 28th day of March, 1997, upon consideration of Sofamor-Danek Defendants' Motion to Reaffirm PTO 12 in Light of *Medtronic, Inc. v. Lohr* and, Alternatively, for Summary Judgment Against Claims Alleging Fraud on the FDA (docket # 5103), and plaintiffs' response thereto, IT IS ORDERED that said motion is GRANTED in part and DENIED in part.

Upon consideration of Sofamor-Danek Defendants' Motion to Substitute Their Motion to Reaffirm PTO 12 for AcroMed Corporation's Motion to Reaffirm PTO 12 (docket # 5160), IT IS ORDERED that said motion is DISMISSED as moot pursuant to the instant Order.

Upon consideration of plaintiffs' Motion to Strike the Motion of the Sofamor-Danek Defendants to Reaffirm PTO 12 in Light of *Medtronic, Inc. v. Lohr* and, Alternatively, for Summary Judgment Against Claims Alleging Fraud on the FDA (docket # 5121), IT IS ORDERED that said motion is DISMISSED as moot pursuant to Pretrial Order No. 759, ¶ 12.

Upon consideration of defendant AcroMed Corporation's Motion to Reaffirm PTO 12 in Light of *Medtronic,. Inc, v. Lohr* (docket # 4814), IT IS ORDERED that said motion is GRANTED in part and DENIED in part for the reasons set forth in the accompanying memorandum.

Upon consideration of defendant Advanced Spine Fixation Systems, Inc. *et al.*'s Motion to Dismiss Fraud on the FDA, Intracompany Conspiracy, and Liability *per se* Claims Made in Amended Omni Complaints (docket # 4950) and plaintiffs' response thereto, IT IS ORDERED that the portion of the motion requesting the dismissal of plaintiffs' fraud-on-the-FDA claim is GRANTED.

/s/ LOUIS C. BECHTLE, J.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

PRETRIAL ORDER NO. 900

AND NOW, TO WIT, this 12th day of May, 1997, upon consideration of defendant Buckman Company's Motion to Dismiss Amended Omni Complaint for Failure to State a Claim Upon Which Relief May Be Granted (docket # 4943), and the opposition thereto, IT IS ORDERED that said motion is GRANTED for the reasons stated in Pretrial Order No. 845.

/s/ LOUIS C. BECHTLE J.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

ALICE and ANGELO ZAMPIRRI, *et al.*

v.

ACROMED CORPORATION, *et al.*

MEMORANDUM AND ORDER

BECHTLE, J. MARCH 2, 1995

Presently before the court is defendants Acromed Corporation and Dr. Arthur Steffee's (collectively "Acromed defendants") motion for partial judgement on the pleadings, and the *Zampirri* plaintiffs[1] response thereto.[2] For the reasons

---

[1] The *Zampirri* plaintiffs' action was consolidated in the Eastern District of Pennsylvania, prior to this case being converted into a multi-district litigation, under the caption *Zampirri et al. v. Acromed*, et al., C.A. No. 93-7074. The *Zampirri* plaintiffs are: Alice and Angelo Zampirri; Margaret and Thomas Thatcher; Joanne and William Watson; Tom and Anita O'Brian; Charles and Kathryn DiRaimondi; Cale Gillette; Vivian Tyson; and Agnes Batezel.

[2] The court has also received the Acromed defendants' reply memorandum in support of its motion; plaintiffs' sur reply memorandum in opposition to defendants' motion for partial judgment on the pleadings; defendants' citation of supplemental authorities relating to its motions for partial judgment on the

set forth below, the Acromed defendants' motion will be granted.

I. INTRODUCTION

This is a products liability action for damages and equitable relief stemming from injuries allegedly suffered by plaintiffs as a result of the surgical implantation of spinal fixation devices into the pedicles of their spines.[3] On August 4, 1994, the Judicial Panel on Multidistrict Litigation converted this action into a multidistrict litigation, transferring all federal pedicle screw cases to this court for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.[4]

The instant motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c) seeks to dismiss the prejudice Counts V, VI and VII of the *Zampirri* plaintiffs' amended and consolidated compliant. Count V charges the Acromed defendants with defrauding the Food and Drug Administration ("FDA"). Count VI charges the Acromed defendants with a violation of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964(c), ("RICO"). Count VII asserts a claim for damages against all defendants under the Lanham Act, 15 U.S.C. § 1125(a). Count VII will be dismissed by way of the attached Order, however, because, as plaintiffs concede in their memorandum of law in opposition to defendants' motion for partial judgement on the pleadings, they lack standing to pursue a Lanham Act claim.

---

pleadings and partial summary judgement; and plaintiffs' reply to defendants' citation of supplemental authorities.

[3] For a thorough recitation of the facts and procedural history of this case, see the court's February 22, 1995 Memorandum and Order, Pretrial Order No. 8.

[4] On February 22, 1995, the court denied the *Zampirri* plaintiffs' motion for class certification. *See* Pretrial Order No. 8.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(c) permits a motion for judgment on the pleadings to be made after the pleadings are closed. Fed. R. Civ. P. 12(c). Under Rule 12(c), judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law. *See McMann v. Phoenix Home Life Mutual Ins. Co.*, No. CIV.A. 94-2229, 1994 WL 410770, at *1 (E.D. Pa. Aug. 4, 1994). When deciding whether to grant a Rule 12(c) motion, the court must view the facts in the light most favorable to the non-moving party. *See Institute for Scientific Information, Inc. v. Gordon and Breach, Science Publishers, Inc.*, 931 F.2d 1002, 1005 (3d Cir.), *cert. denied*, 502 U.S. 909 (1991).

III. DISCUSSION

A. Count V - Fraud on the FDA

In paragraph 107 of their amended and consolidated complaint, the *Zampirri* plaintiffs allege that the Acromed defendants "intentionally, knowing and/or recklessly" misled the FDA when Acromed applied for premarket approval of its nested bone plates and cancellous bone screws. Plaintiffs assert that defendants' fraud on the FDA caused plaintiffs to suffer personal injuries for which there is a private right of action under principles of state law. The Acromed defendants argue that plaintiffs' fraud on the FDA claim should be dismissed because it is preempted by federal law.[5]

[5] Pursuant to the parties' joint Report on Summary Judgment Motions on Preemption, filed with the court on February 28, 1995, the court notes that by way of this Memorandum and Order, the only preemption issue it will resolve at this time is whether a fraud on the FDA claim is preempted by federal law.

Under the law of the Third Circuit, plaintiffs' fraud on the FDA claims against the Acromed defendants must be dismissed because plaintiffs' claims are preempted under the medical device amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k ("FDCA"). *See Michael v. Shiley, Inc.*, No. CIV.A. 94-1496, 1995 WL 45034 (3d Cir. February 7, 1995). In *Michael*, a case with facts similar to the present case, the plaintiff brought negligence, strict product liability, breach of implied warranty of merchantability, breach of express warranty, and common law fraud claims against the manufacturer of a heart value. *See id.* at *1-2. The Third Circuit dismissed plaintiff's fraud on the FDA claims, stressing that section 360k of the medical device amendments to the FDCA does not permit courts to "perform the same function initially entrusted to the FDA." *Id.* at *12. Because the FDA possesses the proper authority to regulate this field, courts are prohibited from conducting "a searching state inquiry into the inner workings of FDA procedures." *Id.*

Plaintiffs argue that *Michael* is distinguishable from the present action and should not control this court's decision on preemption because the Class III medical devices in *Michael* were approved through the FDA's premarket approval process unlike Acromed's Class II bone screws and bone plates which were approved through the "less stringent" FDA premarket notification process. Plaintiffs contend that the preemption of claims relating to medical devices cannot apply to those devices which have not received premarket approval from the FDA. The court, however, disagrees and follows the Fifth Circuit's reasoning in *Reeves v. Acromed Corp.*, No. CIV.A. 93-3752, 1995 WL 29058, at *5 (Feb. 10, 1995), that plaintiffs' "attempt to distinguish this case on the basis of the type of FDA approval process at issue is unpersuasive." In reaching its decision, the *Reeves* court stressed:

> [e]ven if the FDA's Pre-Market Notification process does not result in the FDA's "official approval" of a device,

> the agency subjects the manufacturer's proposed labeling to extensive scrutiny....FDA regulations required AcroMed to submit its proposed labeling with its Pre-Market Notification application. *See* 21 C.F.R. § 807.87(e). The regulations also required the FDA to review AcroMed's labeling to ensure that it was in compliance with the general labeling regulations set out in 21 C.F.R. §§ 801 *et seq*. Therefore, despite the difference between the FDA's Pre-Market Approval and Pre-Market Notification procedures, our preemption analysis remains the same.[6]

Id. As the *Reeves* court stated, "[g]iven the FDA's central role in reviewing and approving devices under the [medical device amendments], the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction." *Id*. at *7.

Finally, "permitting a fraud claim based on false representations to the FDA would conflict with [Third Circuit] precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act." *Michael*, 1995 WL 45034 at *12 (*citing Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994). Thus for the reasons stated in both *Michael* and *Reeves*, the *Zampirri* plaintiffs' fraud on the FDA claims against the Acromed defendants will be dismissed. *See also, King v. Collagen Corp.*, 983 F.2d 1130, 1139-40 (1st Cir. 1993).[7]

---

[6] The court emphasize that by way of this Memorandum and Order, it is not at this time determining whether the scope of preemption for any issue other than fraud on the FDA is the same for Class II and Class III medical devices.

[7] In *Reeves*, the Fifth Circuit noted that the First Circuit, in *King v. Collagen Corp.*, 983 F.2d 1130, 1136, 1139-40 (1st Cir. 1993), is the only other circuit court that has "specifically address[ed] whether evidence of fraud on the FDA is sufficient to defeat preemption under § 360k" of the medical device amendments of the FDCA. *Reeves*, 1995 WL 29058, at *6. In *King*, the First Circuit held that federal law preempted a plaintiff's claim that the manufacturer of a product fraudulently withheld vital safety information from the FDA during the FDA's approval process. 983 F.2d at 1136, 1139-40.

B. Count VI - RICO

Count VI of the *Zampirri* plaintiffs' amended and consolidated complaint charges the Acromed defendants with RICO violations. Paragraph 120 of plaintiffs' complaint asserts that as a result of the Acromed defendants' pattern of racketeering activity, plaintiffs sustained injuries because they "paid excessive amounts" for Acromed's VSP system devices, did not get the pedicle screw system they bargained for, and "incurred [the] additional cost and expense of continued medical treatment." Plaintiffs seek to recover damages for their injuries under the private treble damage remedy provisions of the RICO statute, 18 U.S.C. § 1964(c).

Acromed argues that plaintiffs cannot recover under RICO for their alleged injuries because the RICO statute does not authorize recovery for the types of injuries alleged.

As plaintiffs themselves concede, the RICO statute does not permit recovery of damages for personal injuries. *See* 18 U.S.C. § 1964(c). By its express terms, RICO provides for recovery only for "any person injured in his business or property." 18 U.S.C. § 1964(c). *See Genty v. Resolution Trust Corp.*, 937 F.2d 899, 918-19 (3d Cir. 1991) ("RICO plaintiffs may recover damages for harm to business and property only, not physical and emotional injuries due to harmful exposure to toxic waste."). The court finds that the medical expenses allegedly incurred by plaintiffs are so closely tied to their alleged personal injuries that such expenses cannot be recovered under RICO. *See id*. *See also*,

Doe v. Roe, 958 F.2d 763, 767-68 (7th Cir. 1992); *Grogan v. Platt*, 835 F.2d 844, 846-47 (11th Cir.), *cert. denied*, 488 U.S. 981 (1988). Accordingly, Count VI of plaintiffs' complaint will be dismissed.

IV. CONCLUSION

For the foregoing reasons, the court will grant the Acromed defendants' motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c).

The court rules that the attached Order governs all actions included in MDL 1014 and dismisses all fraud on the FDA, RICO, and Lanham Act claims contained in any such pleading, and it grants any motion currently seeking dismissal of such claims in all MDL 1014 actions.

Currently there are approximately 135 separate actions, representing claims of multiple plaintiffs, included in the MDL 1014 multidistrict litigation. The court has not examined all of those complaints. The court, therefore, bases its present ruling on the understanding that all of the actions and the claims included in MDL 1014 are substantially similar to the action filed by the *Zampirri* plaintiffs, in that the plaintiffs are individuals seeking damages directly or indirectly, primarily for personal injuries allegedly resulting from the surgical implantation of spinal fixation devices into the pedicles of persons identified in each plaintiff's complaint. Any plaintiff whose claim is not of this nature and who believes that the grounds for dismissal relied on by the court in this Memorandum do not apply, may file within fifteen (15) days of the date of this Order, through the Plaintiffs' Legal Committee, a motion for reconsideration setting forth, in fact-specific allegations, how his or her claim differs from that alleged in the *Zampirri* complaint in respect to the criteria the court relied on in making its present ruling supporting the dismissals of three of the *Zampirri* claims.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

ALICE AND ANGLEO ZAMPIRRI, *et al.*

v.

ACROMED CORPORATION, *et al.*

PRETRIAL ORDER NO. 12

ORDER

AND NOW, TO WIT, this 2nd day of March, 1995, upon consideration of defendants Acromed Corporation and Dr. Arthur Steffee's (collectively the "Acromed defendants") motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c), and the *Zampirri* plaintiffs' response thereto, IT IS ORDERED that the Acromed defendants' motion is *granted*.

This Order hereby dismisses all fraud on the FDA, RICO, and Lanham Act claims contained in any pleading, and grants any motion currently seeking dismissal of such claims in all MDL 1014 actions, *except* any action that qualifies for reconsideration, *provided* a motion for reconsideration is filed with the court, in accordance with the court's accompanying Memorandum, within fifteen (15) days of the date of this Order.

/s/ LOUIS C. BECHTLE, J.

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL ACTIONS

MDL DOCKET NO. 1014

PRETRIAL ORDER NO. 106

FINAL JUDGMENT ORDER PURSUANT TO FED.R.CIV.P. 54(b)

AND NOW, this 12th day of September, 1997 upon consideration of Plaintiffs' Motion for Clarification of PTO 900 and for Certification and Entry of a Final Judgment Pursuant to *Fed.R.Civ.P.* 54(b) Dismissing Plaintiffs' Claims Against Defendant Buckman Company Asserted in the Amended "Omni" Complaints and Plaintiffs' Motion for Certification for Immediate Interlocutory Appeal under 28 *U.S.C.* § 1292(b) of Certain Issues Decided in Pretrial Order No. 845, it is hereby

ORDERED, ADJUDGED and DECREED that Plaintiffs' Motion for Clarification of PTO 900 and for Certification and Entry of a Final Judgment Pursuant to *Fed.R.Civ.P. 54(b)* Dismissing Plaintiffs' Claims Against Defendant Buckman Company Asserted in the Amended "Omni" Complaints is GRANTED in part and DENIED in part. The portion of the motion requesting clarification is denied. The portion of the motion requesting final judgment is granted.

IT IS FURTHER ORDERED that the dismissal of the fraud-on-the-FDA claims against Buckman Company ("Buckman") in the amended "Omni" complaints by PTO

900, which refers to and is based on PTO 845, is certified as a final judgment pursuant to *Fed.R.Civ.P.* 54(b) because:

a. The only claims brought against Buckman are claims for fraud-on-the-FDA;

b. in the context of this multidistrict litigation, consisting of approximately 2,300 individual civil actions involving 5,041 plaintiffs suing 334 defendants in 85 districts in 46 states, where hundreds of plaintiffs have brought claims against Buckman and other defendants alleging fraud-on-the-FDA, which the Court dismissed in Pretrial Order Nos. 845 and 900, there is no just reason to delay appeal of this decision dismissing plaintiffs' claim of fraud-on-the-FDA from the litigation;

c. the dismissal of defendant Buckman from the litigation due to the dismissal of plaintiffs' fraud-on-the-FDA claims for the reasons stated in PTO 845 presents a controlling issue of law which. if erroneous, would constitute reversible error on final appeal;

d. the final adjudication of the viability of plaintiffs' fraud-on-the-FDA claims by the Third Circuit Court of Appeals, prior to remand of these hundreds of cases to their transferor districts, as opposed to final adjudication by numerous different Circuit Courts of Appeals, is the best means of achieving the goals of efficient and uniform adjudication of numerous actions for the reasons set forth in *Curtiss-Wright Corp. v. General Electric Co.*, *446* U.S. 1 (1980) and *In re Food Lion, Inc., Fair Labor Standards Act Litig.*, 73 F.3d 528, 533 (4th Cir. 1996), and will materially advance the termination of this multidistrict litigation;

e. the final adjudication of plaintiffs' fraud-on-the-FDA claim is separate, distinct and independent of the claims for design defect, manufacturing defect, failure to warn, breach of warranties, misrepresentation, negligence *per se* and

conspiracy and concert of action remaining in the litigation against remaining defendants;

f. review of this decision by the Third Circuit will not be mooted by any future developments in the case; and

g. no appellate court would have to decide this same issue more than once even if there were subsequent appeals.

The Clerk of the Court is hereby directed to enter a final judgment dismissing plaintiffs' fraud-on-the-FDA claims against Buckman alleged in the amended "Omni" complaints and thereby dismissing Buckman from the litigation.

IT IS FURTHER ORDERED that in light of the above ruling, Plaintiffs' Motion for Certification For Immediate Interlocutory Appeal under 28 *U.S.C.* §1292(b) of Certain Issues Decided in Pretrial Order No. 845 is hereby **DISMISSED as MOOT**.

/s/ LOUIS C. BECHTLE, J.

APPENDIX F

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 97-1783

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION

Plaintiffs Legal Committee, Appellant

SUR PETITION FOR REHEARING

BEFORE: BECKER, *Chief Judge,* SLOVITER, STAPLETON, MANSMANN, GREENBERG, SCIRICA, NYGAARD, ALITO, ROTH, LEWIS, McKEE, RENDELL AND COWEN,* *Circuit Judges*

The petition for rehearing filed by petitioner in the above-entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court en banc, the petition for rehearing is denied. For the reasons set forth in his dissent, Judge Cowen would have granted panel rehearing.

* Hon. Robert E. Cowen, U.S. Circuit Judge for the Third Circuit, assumed senior status before the filing of the petition for rehearing; consequently, his vote is limited to panel rehearing only.

By the Court,

_____

Circuit Judge

DATED: Feb. 03, 1999

APPENDIX G

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.